In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: February 28, 2022

TRAVIS EASON,	*	PUBLISHED
Petitioner,	*	No. 18-406V
v.	*	Special Master Nora Beth Dorsey
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Fact Finding and Ruling on Entitlement; Table Claim; Influenza ("Flu") Vaccine; Guillain-Barré Syndrome ("GBS").
Respondent.	*	

Milton Clay Ragsdale, Ragsdale LLC, Birmingham, AL, for petitioner.
Colleen Clemons Hartley, U.S. Department of Justice, Washington, DC, for respondent.

FACT FINDING AND RULING ON ENTITLEMENT[1]

On March 19, 2018, Travis Eason ("petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program ("Vaccine Act" or "the Program"), 42 U.S.C. § 300aa-10 et seq. (2012),[2] alleging that he suffers from Guillain-Barré Syndrome ("GBS") as the result of an influenza ("flu") vaccination administered on September 12, 2012. Petition at 1-2 (ECF No. 1). Respondent argued against compensation, stating that "this Petition was barred by the Vaccine Act's statute of limitations and compensation should be denied." Respondent's Report ("Resp. Rept.") at 2 (ECF No. 20).

[1] Because this Ruling contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2012). All citations in this Ruling to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

At issue here is petitioner's diagnosis, specifically whether petitioner satisfies the Table criteria for GBS. If petitioner meets the criteria for a GBS Table claim, then the lookback provision of § 16(b) of the Vaccine Act applies, petitioner's petition was timely filed, and petitioner is entitled to compensation. For the reasons stated below, after a review of the record as a whole, including the medical records and the parties' briefs and experts' reports, the undersigned finds that petitioner meets the Table criteria for GBS, and thus, petitioner is entitled to compensation. Petitioner's motion for a ruling on the record is **GRANTED**.

I. ISSUES TO BE DECIDED

The issue to be decided is whether petitioner satisfies the Table criteria for GBS, or whether an alternative diagnosis is more likely.

Petitioner alleges he suffers from GBS as a result of his flu vaccination. Petitioner's Motion for a Ruling on the Record Regarding Petitioner's Diagnosis ("Pet. Mot."), filed June 11, 2021, at 1 (ECF No. 66). Petitioner contends he meets the criteria for a GBS Table claim, and thus, his petition was timely filed pursuant to § 16(b) of the Vaccine Act. Id. at 1-10; Pet. Reply to Resp. Response to Pet. Mot. ("Pet. Reply"), filed Oct. 1, 2021, at 1-3 (ECF No. 74). Additionally, he asserts that he also has filed a timely non-table GBS claim under the lookback provision of § 16(b) "because its likelihood of success was significantly increased by the amendment adding GBS to the Table." Pet. Mot. at 10; see also Pet. Reply at 3-4.

Respondent argues petitioner's diagnosis is multiple sclerosis ("MS") and not GBS and/or transverse myelopathy. Resp. Response to Ruling on the Record ("Resp. Response"), filed Sept. 10, 2021, at 17 (ECF No. 69). Thus, respondent asserts petitioner does not satisfy the Table requirements for a flu/GBS claim and his claim is barred by the Vaccine Act's statute of limitations. Id. at 2, 16-17. Additionally, respondent contends "[t]he lookback provision for Table revisions does not apply because petitioner was eligible to seek compensation prior to the March 21, 2017[] Table change, and that change did not significantly increase his likelihood of receiving compensation based on the facts and circumstances of his case." Id. at 2-3, 18-21. Therefore, respondent argues petitioner's case should be dismissed. Id. at 1, 21.

II. BACKGROUND

A. Medical Terminology

1. Guillain-Barré Syndrome

Under the Vaccine Table Qualifications and Aids to Interpretation, GBS is defined as "an acute monophasic peripheral neuropathy that encompasses a spectrum of four clinicopathological subtypes." 42 C.F.R. § 100.3(c)(15)(i). A presumption of causation is afforded under the Vaccine Injury Table for cases of GBS following flu vaccination if onset is between 3 and 42 days. Id. at § 100.3(a)(XIV)(D).

The four subtypes of GBS are Acute Inflammatory Demyelinating Polyneuropathy ("AIDP"), Acute Motor Axonal Neuropathy ("AMAN"), Acute Motor and Sensory Neuropathy

("AMSAN"), and Fisher Syndrome or Miller Fisher Syndrome ("FS"). Id. at §§ 100.3(c)(15)(ii)-(iii). The diagnosis of AIDP, AMAN, and AMSAN requires:

> (A) Bilateral flaccid[3] limb weakness and decreased or absent deep tendon reflexes in weak limbs;
> (B) A monophasic[4] illness pattern;
> (C) An interval between onset and nadir[5] of weakness between 12 hours and 28 days;
> (D) Subsequent clinical plateau (the clinical plateau leads to either stabilization at the nadir of symptoms, or subsequent improvement without significant relapse; however, death may occur without a clinical plateau); and,
> (E) The absence of an identified more likely alternative diagnosis.

Id. at § 100.3(c)(15)(ii). Supportive, but not required, evidence of a GBS diagnosis "includes electrophysiologic findings consistent with GBS or an elevation of cerebral spinal fluid (CSF) protein with a total CSF white blood cell count below 50 cells per microliter." Id. at § 100.3(c)(15)(iv).

"To qualify as any subtype of GBS, there must not be a more likely alternative diagnosis for the weakness." 42 C.F.R. § 100.3(c)(15)(v). Exclusionary criteria for the diagnosis of GBS include, but is not limited to, the ultimate diagnosis of Chronic Inflammatory Demyelinating Polyneuropathy ("CIDP"),[6] spinal cord infarct, spinal cord compression, subacute inflammatory demyelinating polyradiculoneuropathy, MS, and more. Id. at § 100.3(c)(15)(vi).

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[3] Flaccid means weak. Flaccid, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=18720 (last visited Jan. 31, 2022).

[4] Monophasic means "one phase." Monophasic, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=32043 (last visited Jan. 31, 2022).

[5] Nadir occurs when maximal weakness is attained, or when progression of weakness ceases. See Pet. Ex. 40 at 1 (Yusuf A. Rajabally & Antonio Uncini, Outcome and Its Predictors in Guillain-Barré Syndrome, 83 J. Neurology Neurosurgery & Psychiatry 711 (2012)); Resp. Ex. A, Tab 1 (Arthur K. Asbury & David R. Cornblath, Assessment of Current Diagnostic Criteria for Guillain-Barré Syndrome, 27 Annals Neurology S21 (1990)).

[6] Although the Vaccine Table refers to CIDP as Chronic Immune Demyelinating Polyradiculopathy, the undersigned will refer to it as Chronic Inflammatory Demyelinating Polyneuropathy throughout this Ruling. CIDP is "a slowly progressive, autoimmune type of demyelinating polyneuropathy characterized by progressive weakness and impaired sensory function in the limbs and enlargement of the peripheral nerves, usually with elevated protein in the cerebrospinal fluid." Chronic Inflammatory Demyelinating Polyneuropathy, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=99346 (last visited Jan. 31, 2022). It is "most common[] in young adults, particularly males, and is related to [GBS]. Presenting symptoms often include tingling or numbness of the digits, weakness of the limbs, hyporeflexia or areflexia, fatigue, and abnormal sensations." Id.

2. Multiple Sclerosis

MS is "a disease in which there are foci of demyelination throughout the white matter of the central nervous system, sometimes extending into the gray matter." Multiple Sclerosis, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=105130 (last visited Jan. 31, 2022). Symptoms "include weakness, incoordination, paresthesias, speech disturbances, and visual complaints," and disease course is usually prolonged, with "remissions and relapses that occur over a period of many years." Id. MS typically presents between 20 and 40 years of age. Pet. Ex. 41 at 4.[7]

The International Panel on Diagnosis of Multiple Sclerosis ("International Panel") developed the McDonald criteria, which combines clinical, imaging, and laboratory evidence, to aid in the diagnosis of MS. Pet. Ex. 41 at 1.

The 2017 McDonald Criteria:[8]

	Number of lesions with objective clinical evidence	Additional data needed for a diagnosis of multiple sclerosis
≥2 clinical attacks	≥2	None
≥2 clinical attacks	1 (as well as clear-cut historical evidence of a previous attack involving a lesion in a distinct anatomical location)	None
≥2 clinical attacks	1	Dissemination in space demonstrated by an additional clinical attack implicating a different CNS site or by MRI
1 clinical attack	≥2	Dissemination in time demonstrated by an additional clinical attack or by MRI **OR** demonstration of CSF-specific oligoclonal bands
1 clinical attack	1	Dissemination in space demonstrated by an additional clinical attack implicating a different CNS site or by MRI **AND** Dissemination in time demonstrated by an additional clinical attack or by MRI **OR** demonstration of CSF-specific oligoclonal bands

The International Panel defined the first attack as a "clinically isolated syndrome," or "[a] monophasic clinical episode with patient-reported symptoms and objective findings reflecting a focal or multifocal inflammatory demyelinating event in the [central nervous system ("CNS")], developing acutely or subacutely, with a duration of at least 24 h[ours], with or without recovery, and in the absence of fever or infection." Pet. Ex. 41 at 2. An objective finding is "[a]n

[7] Alan J. Thompson et al., Diagnosis of Multiple Sclerosis: 2017 Revisions of the McDonald Criteria, 17 Lancet Neurology 162 (2018).

[8] Pet. Ex. 41 at 6 (emphasis added).

abnormality on neurological examination, imaging . . . , or neurophysical testing . . . that corresponds to the anatomical location suggested by the symptoms of the clinically isolated syndrome." Id.

The dissemination in time requirement is met when new lesions develop or appear over time. Pet. Ex. 41 at 2. The dissemination in space requirement is met when lesions have developed in distinct anatomical locations within the CNS. Id. In certain situations when dissemination in space is met, but there is no dissemination in time, a finding of oligoclonal bands[9] in the CSF can substitute for the requirement of dissemination in time. Id. at 5. "Although the absence of CSF oligoclonal bands does not rule out multiple sclerosis, particularly early in the condition and in children, caution should be exercised in making this diagnosis when CSF oligoclonal bands are not detected and, certainly, in the presence of atypical clinical, imaging, or CSF findings." Id.

B. Procedural History

Petitioner filed his petition along with medical records on March 19, 2018. Petition; Pet. Exhibits ("Exs.") 1-3. Petitioner filed additional medical records in March and July 2018. Pet. Exs. 4-26. On May 3, 2019, respondent filed his Rule 4(c) Report, and a concurrent motion to dismiss, in which he argued petitioner's "[p]etition was barred by the Vaccine Act's statute of limitations and compensation should be denied." Resp. Rept. at 2; see also Mot. to Dismiss, filed May 3, 2019 (ECF No. 21).

Thereafter, this case was reassigned out of the Special Processing Unit ("SPU") to now-Chief Special Master Corcoran. Notice of Reassignment dated May 7, 2019 (ECF No. 23). Petitioner filed a response to respondent's Motion to Dismiss on May 24, 2019, and respondent filed a reply on May 31, 2019. Pet. Brief in Opposition to Resp. Rept. & Mot. to Dismiss, filed May 24, 2019 (ECF No. 25); Resp. Reply in Support of Mot. to Dismiss, filed May 31, 2019 (ECF No. 26). Chief Special Master Corcoran deferred ruling on the Motion to Dismiss because further substantiation of the record was required. Order dated June 28, 2019 (ECF No. 28).

This case was reassigned to the undersigned on October 3, 2019. Notice of Reassignment dated Oct. 3, 2019 (ECF No. 31). Petitioner filed updated neurology records on April 17, 2020, and an expert report from Dr. Shin Oh on May 18, 2020. Pet. Exs. 27-29. Respondent filed an expert report from Dr. Peter D. Donofrio on July 24, 2020. Resp. Exs. A-B. On August 19, 2020, petitioner filed updated medical records. Pet. Exs. 30-31.

The undersigned held a status conference on August 20, 2020. Order dated Aug. 20, 2020 (ECF No. 45). After a review of the medical records, expert reports, and parties' briefs, the undersigned denied respondent's Motion to Dismiss because petitioner's diagnosis remained a

[9] Oligoclonal bands are "discrete bands of immunoglobulins with decreased electrophoretic mobility; their appearance in electrophoretograms of [CSF] when absent in the serum is a sign of possible [MS] or other diseases of the central nervous system." Oligoclonal Bands, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=60106 (last visited Jan. 31, 2022).

disputed issue of material fact. Id. at 1-2. Petitioner was directed to file a responsive expert report. Id. at 2.

In October 2020, petitioner filed medical records and a responsive expert report from Dr. Oh. Pet. Exs. 32-37. Respondent filed a supplemental expert report from Dr. Donofrio on January 28, 2021. Resp. Ex. C. On June 11, 2021, petitioner filed medical records, a supplemental expert report from Dr. Oh, and a Motion for Ruling on the Record. Pet. Exs. 38-41; Pet. Mot. Respondent filed a response to petitioner's Motion on September 10, 2021, and petitioner filed his reply on October 1, 2021. Resp. Response; Pet. Reply.

This matter is now ripe for adjudication.

C. Factual History

1. Medical History

a. Medical History Prior to Vaccination

Petitioner's past medical history is significant for hypertension, obesity, diabetes mellitus (type II), Charcot foot disease, myocardial infarction, coronary stent placement, obstructive sleep apnea, and toe amputations. Pet. Ex. 4 at 10, 18; Pet. Ex. 19 at 32.

In 2009, petitioner was noted to "ha[ve] been diabetic for about 20 years" and he was "aware that he ha[d] lost sensation in his feet." Pet. Ex. 25 at 183. In 2010, he was diagnosed with diabetic peripheral neuropathy. Id. at 135. He was also found to have diabetic retinopathy[10] in 2010, and "numbness on bottom of feet." Pet. Ex. 22 at 8-11.

b. Vaccination and Medical History in 2012

On September 10, 2012, petitioner saw his endocrinologist, Dr. Mary Casals, who noted petitioner had not been checking his blood glucose levels and had been frequently suspending his insulin pump. Pet. Ex. 22 at 26.

On September 12, 2012, petitioner received a flu vaccine at 49 years of age. Pet. Ex. 1 at 4-7; Pet. Ex. 3 at 1.

Petitioner visited East Alabama Medical Center Emergency Department ("ED") on September 17, 2012, complaining of a productive cough with "slightly yellow" and "blood tinged sputum over the past few days." Pet. Ex. 23 at 293. He reported a fever at home. Id. He also stated he was "a little short of breath, not exceptionally short of breath," with no chest tightness. Id. Physical examination was normal. Id. at 293-94. Dr. Rick Ledkins noted petitioner "felt significantly better after staying [] in the [ED]. He has had cough, cold-like

[10] Diabetic retinopathy is "retinal changes associated with diabetes mellitus." Diabetic Retinopathy, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=103910 (last visited Jan. 31, 2022).

symptoms." Id. at 294. Dr. Ledkins felt petitioner's condition was pulmonary and not cardiac in nature. Id. Diagnosis was upper respiratory infection/bronchitis. Id. at 292, 294. Petitioner was prescribed a Z-Pak and discharged home. Id. at 294.

Approximately one week later, on September 24, 2012, petitioner saw his cardiologist, Dr. Donald W. Rhodes. Pet. Ex. 20 at 21. He exhibited elevated blood pressure. Id. No neurological or respiratory issues or complaints were noted.

On the morning of October 1, 2012, petitioner presented to the emergency room ("ER") at Community Hospital.[11] Pet. Ex. 7 at 2. Chief complaint was lower back pain that started three weeks ago after twisting and leg numbness that began that day. Id. at 2, 5. He reported the pain radiated down both thighs and legs and was exacerbated with movement and standing. Id. at 5. Petitioner reported a pain level of 9 out of 10 and 10 out of 10. Id. at 2, 5. Petitioner also reported weakness of both legs. Id. at 5. Neurological physical examination was normal. Id. at 4. Physical examination of his back revealed tender paraspinal muscles and tender midline. Id. at 5. A lumbar spine X-ray revealed minimal degenerative changes. Id. at 6. Petitioner was diagnosed with a lumbar strain. Id. at 7. He was given medication[12] and discharged home in stable condition. Id. at 2. Pain at discharge was 2 out of 10. Id.

Later that day, petitioner presented to Dr. Melvin D. Russell for back pain and numbness in his legs. Pet. Ex. 24 at 13. Petitioner stated he went to the ER that morning. Id. He reported a "sudden onset of numbness from his waist down," difficulty walking, and pain of 9 out of 10. Id. Petitioner explained that "he might have strained his back three weeks ago and he saw a chiropractor last Thursday," September 27, 2012. Id. Dr. Russell noted "[w]ith this sudden onset and the fact that he is numb from his waist down does concern [him]." Id. Physical examination revealed "[v]ery positive leg raising bilaterally with subjective numbness from his waist down." Id. at 14. Petitioner could barely walk and was using an umbrella as a cane. Id. Assessment was lumbago[13] and peripheral neuropathy. Id. Dr. Russell explained that he was going to find a neurologist to see petitioner as soon as possible to "be sure this is not [] transverse myelitis" ("TM").[14] Id.

The following day, October 2, 2012, petitioner saw neurologist, Dr. Larry W. Epperson, on referral from Dr. Russell for "sudden flaccid weakness and altered sensation below the waist

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[11] These records are difficult to read.

[12] According to records from Dr. Epperson the following day, petitioner "was given [prescriptions for] Norflex and Naprosyn but did not get them filled." Pet. Ex. 4 at 10.

[13] Lumbago refers to "any pain in the lower back." Lumbago, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=28856 (last visited Jan. 31, 2022).

[14] TM is a "myelitis in which the functional effect of the lesions spans the width of the entire cord at a given level." Transverse Myelitis, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=91212 (last visited Jan. 31, 2022).

which has continued for 24 hours." Pet. Ex. 4 at 9. Petitioner reported numbness and tingling in lower extremities, and denied muscle weakness in upper extremities. Id. Petitioner explained that he experienced back pain three weeks ago when he twisted his body to the right and felt a sudden sharp pain in his lower lumbar area. Id. The pain has continued but subsided and would be worse when he bent over or sat down. Id. He visited a chiropractor for an adjustment last Thursday. Id. Twenty-four hours ago, petitioner fell because he had no feeling in his lower part of his body and complete muscle weakness. Id. Petitioner denied weakness in his upper extremities. Id. He also reported loss of bladder control for two days and no bowel movements for past two days. Id. At the time of this visit, petitioner was able to move his extremities, but Dr. Epperson noted they were very weak, with the left weaker than the right. Id.

Physical examination revealed 5/5 motor strength, sensory examination showed absent vibratory responses in the lower extremities up to mid-thigh with altered sensation below T10 anteriorly, impaired proprioception bilaterally in the lower extremities, fasciculations in his lower extremities, lower extremity weakness, and normal deep tendon reflexes. Pet. Ex. 4 at 13. Dr. Epperson's impression was "[s]udden onset flaccid paralysis with decreased lower extremity sensation with associated back pain, which started over 24 [hours] ago." Id. at 14. Because of petitioner's sudden onset of urinary incontinence, loss of pain and temperature sensation, and hemiparesis in lower extremities, Dr. Epperson thought petitioner could be suffering from a spinal cord compression and/or spinal cord infarction. Id. He ordered magnetic resonance imaging ("MRI") and magnetic resonance angiography ("MRA") of the lumbar and thoracic spines. Id. He believed GBS could be ruled out "since weakness [was] confined to the lower extremities and not ascending to upper extremities." Id.

The thoracic spine MRI revealed minimal multilevel disc desiccation without significant effacement of the thecal sac or neural foraminal stenosis identified. Pet. Ex. 4 at 88. Some degenerative changes within the cervical spine were noted. Id. The lumbar spine MRI revealed multilevel lumbar spondylosis, most pronounced at L4-L5 where there was a central disc protrusion. Id. at 89. Neither study was interpreted as showing TM.

On October 4, 2012, petitioner presented to the ED at Jackson Hospital after falling face first. Pet. Ex. 6 at 118. Petitioner also complained of a history of low back pain, pain in both legs, and left thoracic pain. Id. at 118-19. Petitioner stated he had a lower back injury one week prior and then began having left leg numbness. Id. at 119. At the time of this visit, his MRI results were not yet released. Id. Petitioner explained that he was "walking down the stairs this morning and fell on some rocks face first." Id.

Physician Assistant ("PA") Robert Cibiras also documented petitioner's history of present illness. Pet. Ex. 6 at 120. Petitioner "state[d] that the entire lower half of his body has been numb for the last 4 days." Id. He had been using a cane for ambulation. Id. Earlier that morning, "he was walking down the stairs when his legs gave way." Id. He continued to complain of lower body numbness. Id. Physical examination revealed full flexion and extension, good strength, normal spine and pelvis exam, good non tender axial rotation and flexion, and normal muscle strength. Id. at 121. A chest X-ray was conducted and found petitioner fractured the eighth and ninth ribs on his left side. Id. at 121, 130. Petitioner was discharged home in stable condition. Id. at 122.

Petitioner returned to Dr. Epperson on October 8, 2012 for electromyography/nerve conduction velocity ("EMG/NCV") testing. Pet. Ex. 4 at 16. Dr. Epperson noted petitioner required a wheelchair now and was disabled. Id. Petitioner reported his numbness increased from the T-T10 area to his mid chest. Id. Physical examination revealed "sensory level around T6-T7 with paraparesis" and "grossly normal reflexes absent upper alteration."[15] Id. at 17. His EMG was normal. Id. at 90. However, his NCV findings were indicative of a severe diffuse sensorimotor peripheral neuropathy in the left and right lower extremity and right upper extremity compatible with GBS. Id. Impression was "severe diffuse neuropathy in the lower extremities and right upper extremity compatible with [GBS] versus a severe neuropathy from diabetes." Id. at 18. A lumbar puncture was ordered, and petitioner was referred to neuromuscular specialist Dr. Shin Oh. Id.

Petitioner underwent a lumbar puncture on October 15, 2012. Pet. Ex. 4 at 94; Pet. Ex. 12 at 37. Petitioner's CSF revealed elevated protein of 75 (range 15-45). Pet. Ex. 12 at 32. Petitioner's CSF cultures and gram stains and smears were negative, as were his cryptococcus and bacterial antigen tests. Id. at 34-35.

On October 22, 2012, petitioner saw Dr. Keith A. Thompson on referral from Dr. Epperson. Pet. Ex. 6 at 31. Under history of present illness, Dr. Thompson documented that NCV studies showed petitioner had increasing neuropathy that recently advanced to the T10 area of the mid-chest. Id. Petitioner "presented with paraparesis that [was] fairly abrupt onset over about a month, so it was felt like he had [GBS] and was referred for [intravenous immune globulin ("IVIG")]." Id. Petitioner was in a wheelchair at this visit. Id. Under review of systems, petitioner reported "weakness to near paralysis over the past two weeks." Id. Physical examination revealed "profound weakness up to T-10." Id. Primary diagnosis was acute infective polyneuritis. Id. Dr. Thompson noted that petitioner had an "[a]cute onset [GBS] with paralysis up to T10" and he planned to start petitioner on IVIG. Id. at 32. Petitioner received IVIG from October 23 to October 26, 2012. Id. at 29.

Petitioner returned to Dr. Thompson on October 30, 2012 for a follow up on his response to IVIG treatments. Pet. Ex. 6 at 29. Petitioner "report[ed] that he can move his leg and foot much better now. He [was] able to ambulate with his crutches, although he cannot go very far because he feels like his leg is about to give out." Id. Diagnosis was GBS. Id. at 30. Petitioner was to follow up with Dr. Thompson in two weeks to determine if further IVIG would be needed. Id.

Petitioner saw Dr. Thompson on November 13, 2012. Pet. Ex. 6 at 27. He noted that petitioner required occasional assistance, but was able to care for most of his needs. Id. at 28. Dr. Thompson planned to continue petitioner on IVIG. Id.

Petitioner presented to East Alabama Medical Center ED on December 14, 2012 for increasing shortness of breath over the past couple of days with some chest tightness. Pet. Ex. 23

[15] It is not clear what Dr. Epperson meant in this note due to lack of punctuation and misspellings.

at 249, 275. Petitioner reported a history of GBS and noted he had been receiving IVIG and had been very sedentary. Id. at 249. He was admitted for an exacerbation of congestive heart failure and uncontrolled hypertension. Id. at 250, 268. Petitioner was discharged on December 17, 2012 with diagnoses of acute on chronic systolic heart failure, ischemic cardiomyopathy, hypertension, and diabetes mellitus. Id. at 267.

On December 19, 2012, petitioner saw Dr. Thompson for a follow up on his GBS. Pet. Ex. 6 at 25. Petitioner was doing well and had no new problems. Id. Diagnosis remained GBS. Id. Dr. Thompson noted petitioner engaged in normal activity with effort, and was in stable condition. Id. at 26.

Petitioner saw Dr. Michael P. Massey for papilledema in both eyes on December 21, 2012. Pet. Ex. 16 at 28. Dr. Massey noted petitioner "has significant background diabetic retinopathy with a very swollen and hemorrhagic disc in both eyes." Id. Petitioner reported he was receiving IVIG for GBS over the past two months. Id. Dr. Massey noted "[s]wollen optic nerves are a known complication of [GBS], but [petitioner] has not had a recent MRI of the brain." Id. A brain MRI was ordered because Dr. Massey thought petitioner may have increased intracranial pressure as a complication of his GBS. Id. A brain MRI with and without contrast and a head MRA were conducted that day. Pet. Ex. 12 at 29-30. The brain MRI found "multifocal areas of signal abnormality within portion of the white matter of both hemispheres," which was "somewhat greater than expected for the age of the patient." Id. at 30. Given this appearance, a demyelinating disorder could not be excluded; however, diabetes was listed as a chronic illness "that may account for this finding." Id.

c. Medical History in 2013

Petitioner underwent a lumbar puncture on January 8, 2013. Pet. Ex. 4 at 97; Pet. Ex. 12 at 26. Petitioner's CSF showed a high protein of 52 (range 15-45). Pet. Ex. 12 at 23. His CSF also revealed a high white blood cell count (13 and 9; range 0-5), no oligoclonal bands in the CSF or serum, high IgG in the CSF and serum, and high albumin in the CSF. Id. at 24-25.

Petitioner returned to his cardiologist, Dr. Rhodes on January 10, 2013. Pet. Ex. 20 at 22. Dr. Rhodes documented petitioner's recent GBS diagnosis and his IVIG treatment schedule. Id.

On January 29, 2013, petitioner returned to Dr. Thompson for a GBS follow up. Pet. Ex. 6 at 23. Petitioner was still on IVIG. Id. Petitioner was no longer in a wheelchair and was using a cane to walk. Id. Neurologic physical examination revealed 2/4 strength in left lower extremity. Id. Dr. Thompson ordered petitioner to continue IVIG for four days every 28 days. Id. at 24.

On February 4, 2013, petitioner saw Dr. Epperson for a follow up on his GBS. Pet. Ex. 4 at 20. Petitioner reported he felt better, but complained of blurred vision and muscle spasms in his left calf. Id. He was walking with a cane. Id. Dr. Epperson noted that although the December 2012 MRI could not exclude a demyelinating disease, petitioner's MS profile was negative. Id. Physical examination revealed "sensory level around T6-T7 with paraparesis" and

"grossly normal reflexes absent upper alteration."[16] Id. at 21. Additionally, Dr. Epperson found motor examination was 5/5, sensory examination was normal, gait and station were normal, no ataxia, and normal deep tendon reflexes. Id. Dr. Epperson's impression remained "severe diffuse neuropathy in the lower extremities and right upper extremity compatible with [GBS] versus a severe neuropathy from diabetes." Id. at 22. He also noted petitioner's papilledema diagnosis from Dr. Massey. Id.

The next day, on February 5, 2013, petitioner saw Dr. Oh at the University of Alabama Birmingham ("UAB") Neuromuscular Disease Clinic. Pet. Ex. 5 at 1. Chief complaint was GBS, and petitioner complained of visual disturbances. Id. Petitioner reported that "[o]n October 1, 2012, he woke up with numbness and loss of sensation and weakness in legs." Id. at 2. He reported he had bronchitis two weeks prior to his onset and his flu shot prior to that. Id. He was completely paralyzed in his legs and wheelchair bound. Id. He received a diagnosis of GBS, and he has received IVIG four days per month since. Id. Petitioner reported his paralysis was improving and he had been walking without a wheelchair for three weeks. Id. He had no bowel or urination problem. Id. He felt "numb up to the lower belly level." Id. Neurological physical examination revealed scotoma[17] in both eyes, hemorrhage in the optic disc bilaterally, pin-prick sensory loss below T10 and in both legs, normal motor function, sensory function position absent on toes, moderately decreased vibration on ankles and absent on toes, wide-based gait, normal reflexes in knees, triceps, and biceps, and decreased reflexes in ankles.[18] Id. Diagnostic impression was atypical GBS with transverse myelopathy. Id. at 3. Dr. Oh found the NCV study showed demyelinating neuropathy, and history and findings were typical of GBS. Id. Dr. Oh found T10 sensory loss atypical. Id. Dr. Oh found no evidence of recurrence of GBS. Id. Dr. Oh recommended Dr. Epperson reduce the frequency of petitioner's IVIG and decide whether it was needed. Id. Dr. Oh performed EMG/NCV studies that day that revealed findings "indicative of chronic demyelinating polyneuropathy in the upper and lower extremities." Id. at 8.

Petitioner saw Dr. Massey on February 12, 2013. Pet. Ex. 16 at 26. Dr. Massey wrote that he spoke to Dr. Oh and they discussed whether petitioner could be suffering from GBS or MS. Id. The following day, petitioner was found to have "electrophysiological evidence of a dysfunction of the bilateral [visual evoked potentials] systems." Pet. Ex. 4 at 98.

As an outpatient, petitioner visited Jackson Hospital & Clinic from February 18 to February 22, 2013. Pet. Ex. 25 at 69-111. Dr. Epperson ordered administration of Solu-

[16] This note is unchanged from petitioner's visit to Dr. Epperson on October 8, 2012. Compare Pet. Ex. 4 at 17, with Pet. Ex. 4 at 21.

[17] Scotoma is "an area of lost or depressed vision within the visual field, surrounded by an area of less depressed or of normal vision." Scotoma, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=45100 (last visited Jan. 31, 2022).

[18] Dr. Oh's note documented reflexes were "++/++ in knee, biceps, and triceps" and ankle reflexes were "-/+." Pet. Ex. 5 at 2.

Medrol[19] for five days. Id. at 70. The ambulatory care note documented petitioner's diagnosis as MS. Id. at 69. The nursing progress notes explained petitioner was there for "treatment for [MS]" and "MS symptoms." Id. at 76, 78, 81.

On February 26, 2013, petitioner saw Dr. Thompson, who gave him "IV fluids and IV insulin [] to try to get his blood sugars under control." Pet. Ex. 6 at 21-22. Petitioner returned to Dr. Thompson on March 5, 2013. Id. at 19. Petitioner reported his blurred vision and lower extremity weakness were improving. Id. Petitioner was to continue with IVIG four days every 28 days. Id. at 20.

Petitioner saw Dr. Casals, his endocrinologist, on March 6, 2013 for a diabetes follow up. Pet. Ex. 22 at 28. Petitioner reported his hospitalization for GBS and current IVIG treatment schedule, and stated it was his last day of steroids for macular edema. Id. He reported highly elevated blood sugars and blood glucose levels frequently above 400. Id. She found his diabetes was very poorly controlled and exacerbated by steroids. Id. at 31. He was instructed to avoid prolonged insulin pump suspensions. Id.

On March 11, 2013, Dr. Massey documented that he spoke with Dr. Epperson and Dr. Oh. Pet. Ex. 16 at 26. Dr. Epperson noted petitioner did not have MS. Id. Dr. Oh noted that petitioner could have "chronic demyelinating polyneuropathy (GB)". Id.

On April 2, 2013, petitioner returned to Dr. Thompson's office and saw Certified Registered Nurse Practitioner ("CRNP") Kristi Springer. Pet. Ex. 6 at 17. Petitioner reported Dr. Epperson ordered IVIG five days every 28 days. Id. Additionally, he reported the five-day regimen of Solu-Medrol improved his blurry vision. Id. Petitioner "report[ed] feeling heaviness in his legs with difficulty ambulating as it is closer to time for him to receive IVIG." Id. Physical examination revealed no localized motor or sensory findings. Id. at 18. On the following day, petitioner returned to Dr. Massey and reported the steroids "helped a little bit." Pet. Ex. 16 at 26. Examination revealed both eyes were "definitely better." Id. at 25.

Petitioner returned to Dr. Epperson on May 6, 2013. Pet. Ex. 4 at 24. He was still doing IVIG treatments monthly, and he reported feeling better. Id. Dr. Epperson's impression remained unchanged, and the diagnosis remained GBS. Id. at 26. Dr. Epperson noted that Dr. Oh agreed with the GBS diagnosis. Id. Dr. Epperson's plan was to decrease IVIG to twice every month for four months if renal function was good. Id. at 27.

In July and September 2013, petitioner saw Dr. Massey. Pet. Ex. 16 at 23-24. His vision was improving. Id. at 23. Dr. Massey noted petitioner's diabetes and GBS were affecting his vision. Id.

[19] Solu-Medrol "is a prescription medicine used to treat the symptoms of Allergic Conditions and Acute Exacerbations of [MS]." Solu Medrol, RxList, https://www.rxlist.com/solu-medrol-drug.htm (last updated June 7, 2021).

d. Medical History in 2014

Petitioner visited cardiologist, Dr. Renzo Y. Loyaga-Rendon, at the Advanced Heart Failure Clinic at UAB on January 9, 2014, on referral from Dr. Rhodes. Pet. Ex. 15 at 14. Petitioner reported that as a result of his GBS, he "lost some control of his lower extremities," he had no "sensory capabilities up to the abdomen," and he "use[d] a cane to walk." Id. at 15. Under review of systems, he reported worsening eyesight but no recent visual problems or nerve damage in his feet. Id. at 16. Physical examination revealed sensory deficits in lower extremities. Id. at 17. Dr. Loyaga-Rendon noted petitioner was not adhering to his diet and restrictions. Id. at 18.

On January 13, 2014, petitioner returned to Dr. Epperson. Pet. Ex. 4 at 29. Dr. Epperson noted petitioner had not received IVIG for the past five to six months. Id. Petitioner was without insurance for several months, and now that he had insurance again, petitioner felt he needed to restart IVIG treatments. Id. Physical examination revealed 4/5 motor strength bilaterally in the anterior tibialis and gastrocnemius muscles, absent vibratory response in lower extremities up to mid-thigh, altered sensation below T10 anteriorly, impaired proprioception bilaterality in lower extremities, poor finger to nose and range of motion, ataxic gait, difficulty with tandem gait, lower extremities weakness, partial footdrop bilaterally, and decreased reflexes. Id. at 31-32. Petitioner underwent EMG/NCV studies that revealed "electrophysiological evidence of a severe diffuse sensorimotor peripheral neuropathy compatible with [GBS] and a right S1 and Left L4-5 radiculopathy vs a diabetic radiculopathy vs an axonal neuropathy." Id. at 100-01. Dr. Epperson's findings were "compatible with GBS and not diabetic neuropathy." Id. at 33. IVIG was ordered on a decreasing regime each month. Id.

Petitioner returned to Dr. Loyaga-Rendon on March 21, 2014 for a follow up. Pet. Ex. 15 at 5. Dr. Loyaga-Rendon noted petitioner's diabetes was "out of control" and "advised that if his glucose continues to be this elevation, he should seek medical attention." Id. at 8. His glucose was 494 (range 70-100). Id. at 9.

On April 16, 2014, petitioner visited Dr. Epperson for a follow up. Pet. Ex. 4 at 36. Petitioner had three IVIG treatments the previous month and felt it helped. Id. Diagnoses included GBS, diabetic neuropathy, hypertension, and hyperlipidemia. Id. at 41. Petitioner returned to Dr. Epperson next on June 5, 2014. Id. at 42. Dr. Epperson noted petitioner did not receive IVIG treatments for the previous two months due to an increase in blood urea nitrogen and creatine that had normalized. Id. Diagnoses included GBS, diabetic neuropathy, hypertension, and hyperlipidemia. Id. at 48.

Petitioner underwent EMG/NCV studies on August 20, 2014, which revealed "electrophysiological evidence of a severe diffuse sensorimotor peripheral neuropathy in the upper and lower extremities and right arm most likely [from] GBS/CIDP." Pet. Ex. 4 at 1. When compared to his last EMG/NCV from January 2014, no improvement was noted. Id. Due to these findings, Dr. Epperson determined petitioner needed IVIG once Dr. Michael H. Broder approved his renal function. Id. at 59-60. Diagnoses included GBS, diabetic neuropathy, hypertension, hyperlipidemia, and renal insufficiency. Id. at 60-61.

On September 9, 2014, petitioner saw Dr. Russell for a medication refill. Pet. Ex. 19 at 23. Neurological physical examination noted petitioner's deep tendon reflexes were equal bilaterally, sensory intact with muscle strength of 5/5, and gait intact with no cerebellar signs. Id. at 24. Petitioner returned to Dr. Russell's office on November 24, 2014 after slipping in the bathroom and hurting his right knee and saw Ginger W. McDougal, CRNP. Id. at 26. Physical examination noted he was using a cane for ambulation, but did not indicate if this was due to the fall or GBS sequalae. Id. at 27. Neurological physical examination revealed normal motor strength, normal deep tendon reflexes, and a normal gait. Id.

e. Medical History in 2015

On January 5, 2015, petitioner returned to Dr. Epperson. Pet. Ex. 4 at 62. During the visit, petitioner had a boot on his right foot due to a fracture. Id. Dr. Epperson wrote Dr. Broder ordered petitioner to stop IVIG treatments due to his abnormal kidney function. Id. Diagnoses included acute infective polyneuritis, chronic inflammatory demyelinating polyneuritis, polyneuropathy in diabetes, hyperlipidemia, hypertension, and unspecified disorder of kidney and ureter. Id. at 67.

On January 30, 2015, petitioner saw Dr. Massey for distorted vision. Pet. Ex. 16 at 15. By March 2015, petitioner reported everything was blurry. Id. at 14. Although his vision remained distorted, he reported his vision was getting better in April 2015. Id. His vision continued to be blurry at his follow up visits to Dr. Massey for the remainder of 2015. Id. at 12-13.

Petitioner presented to Baptist Medical Center East on April 2, 2015 for diabetic foot ulcer/puncture wound with nail and mild cellulitis. Pet. Ex. 19 at 58. Petitioner reported he did not feel the nail go through his boots due to his GBS. Id. He received a tetanus shot. Id. Dr. Lois J. Shulman noted petitioner had peripheral neuropathy secondary to GBS and diabetes. Id.

On April 6, 2015, petitioner saw Dr. Thompson who noted petitioner returned to receive IVIG two days per month. Pet. Ex. 6 at 15. He returned on May 4, 2015 and "report[ed] his legs fe[lt] less heavy, and he [was] ambulating much better" after two infusions of IVIG the previous month. Id. at 13. Petitioner was still using a cane to ambulate. Id. Petitioner was directed to continue with two infusions of IVIG per month. Id. at 14.

On April 21, 2015, petitioner saw Dr. Russell for a checkup and lab work. Pet. Ex. 19 at 29. Under review of symptoms, Dr. Russell wrote petitioner has a peripheral neuropathy secondary to his diabetes. Id. Physical examination revealed petitioner was limping and using a cane to steady himself. Id. at 30. A neurologic examination was not done. Id.

Petitioner was receiving two infusions of IVIG each month, and reported his symptoms continued to improve on July 8, 2015. Pet. Ex. 6 at 11. Petitioner returned to Dr. Epperson on July 14, 2015. Pet. Ex. 4 at 49. Dr. Epperson wrote "[petitioner] state[d] his CIDP is progressing." Id. Petitioner was receiving IVIG, but due to his decreased renal function, it was being discontinued. Id. Dr. Broder told petitioner that there was a possibility of dialysis in one year. Id. Diagnoses included acute infective polyneuritis, chronic inflammatory demyelinating

polyneuritis, polyneuropathy in diabetes, end stage renal disease, hypertension, and hyperlipidemia. Id. at 54.

In September 2015, petitioner fell into a fire, suffering burns to his right knee and a right wrist fracture. Pet. Ex. 37 at 66; Pet. Ex. 7 at 8-11; Pet. Ex. 9 at 8. He received surgery on his right wrist on September 23, 2015. Pet. Ex. 9 at 6-7.

On October 13, 2015, petitioner returned to Dr. Thompson, who noted petitioner's renal function was good and ordered petitioner to continue IVIG twice monthly. Pet. Ex. 6 at 9-10.

f. Medical History in 2016

Petitioner returned to Dr. Thompson on January 8, 2016. Pet. Ex. 6 at 7. Dr. Thompson noted petitioner was supposed to receive IVIG two days every month, but he went out of town "for an extended period of time and opted not to resume his treatments until now." Id. Dr. Thompson ordered petitioner to continue with IVIG. Id. at 8.

On February 8, 2016, petitioner saw Dr. Epperson who noted petitioner was receiving IVIG twice a month. Pet. Ex. 4 at 68. Petitioner reported the IVIG treatments were helping his walking and made his legs feel less heavy. Id. He was to continue receiving IVIG as long as creatine and BUN levels remained normal. Id. at 72. Diagnoses included GBS, end stage renal disease, and hyperlipidemia. Id. at 73.

On March 8, 2016, petitioner underwent surgery to place an epicardial left ventricular lead. Pet. Ex. 19 at 108-10; Pet Ex. 23 at 7-57. On March 31, 2016, petitioner saw Dr. Rhodes and reported he was doing "very well" and "has walked more than he has in the past." Pet. Ex. 20 at 48.

On July 28, 2016, petitioner presented to Jackson Hospital Wound Care Clinic "complaining of a thick callus with a narrow open skin defect on the plantar surface of the left foot" that "has been present for approximately three weeks." Pet. Ex. 25 at 15. Dr. Randall Cook noted "[b]oth feet [were] insensate as a result of diabetic peripheral neuropathy and [petitioner] was not aware of the presence of the lesion until his wife brought it to his attention." Id. Physical examination revealed "reduced sensation across the plantar surfaces of both feet consistent with diabetic peripheral neuropathy." Id. at 16. Impression included dyshidrosis[20] of the plantar surface of the skin of both feet, diabetic peripheral neuropathy, and history of GBS. Id.

Petitioner saw Dr. Epperson on September 2, 2016. Pet. Ex. 4 at 74. Petitioner was still receiving IVIG treatments two days per month. Id. Physical examination revealed a decreased sensation in a stocking glove distribution and absent deep tendon reflexes, but was otherwise unchanged. Id. at 76. Impression was GBS versus CIDP. Id. at 77.

[20] Dyshidrosis is "any disorder of the eccrine sweat glands." Dyshidrosis, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=15212 (last visited Jan. 31, 2022).

On December 1, 2016, petitioner saw Dr. Thompson who noted petitioner continued to receive IVIG. Pet. Ex. 6 at 3. Petitioner continued to report that when he does not receive treatment, or when it is close to his treatment date, his legs feel heavy, "meaning he is developing some increasing neurologic symptoms." Id. Dr. Thompson found petitioner "seem[ed] to be doing well overall," and ordered petitioner to continue IVIG once per month. Id. at 4.

g. Medical History in 2017

On January 23, 2017, petitioner presented to the Baptist Health Neurology Clinic to re-establish care regarding his history of obstructive sleep apnea. Pet. Ex. 27 at 131. His history of GBS was noted as well as his residual leg weakness that was being treated by Dr. Epperson. Id. He reported blurry and double vision, back pain, neck pain, difficulty walking, balance trouble, neuropathy, and snoring. Id. at 131-32. Physical examination by Nurse Practitioner ("NP") Jessica Adair revealed 5/5 strength throughout, sensation decreased to vibration in stocking distribution bilaterally, symmetric reflexes, and a steady gait with use of a cane. Id. at 132.

On June 1, 2017, petitioner saw Ms. Springer at Montgomery Cancer Center. Pet. Ex. 6 at 1. Ms. Springer noted petitioner was receiving IVIG two days each month. Id. Petitioner was still reporting heaviness in his lower extremities near the date of treatment, especially in his left lower extremity, which improves after treatment. Id. Petitioner was ambulatory with a cane. Id. She noted petitioner was "mildly thrombocytopenic today with a platelet count of 119,000. His platelet count tends to wax and wane. He continues with a mild anemia which remains stable as well." Id. at 2. Plan was to have petitioner continue with IVIG treatments two days each month. Id.

On June 23, 2017, petitioner saw Dr. Epperson. Pet. Ex. 8 at 3. Petitioner reported "[h]is feet and legs continue to be numb" and he "continu[es] to fall and ambulate[] with a cane." Id. Impression remained GBS versus CIDP. Id. at 6. He was to continue receiving IVIG treatments two days each month. Id. at 6-8. Diagnoses included GBS, end stage renal disease, hyperlipidemia, and chronic inflammatory demyelinating polyneuritis. Id. at 8. Petitioner underwent EMG/NCV studies that found evidence of "a severe peripheral neuropathy in the lower extremities compatible with [GBS]/CIDP with possible superimposed diabetic peripheral neuropathy. There [was] no electrophysiological evidence of a bilateral L3-S1 radiculopathy." Pet. Ex. 4 at 5-6. Additionally, when compared to the previous tests in 2015, minimal improvement was found." Id. at 6.

h. Medical History in 2018

On February 21, 2018, petitioner returned to Dr. Epperson. Pet. Ex. 17 at 137. Petitioner was continuing with IVIG treatments twice each month. Id. at 138. Petitioner reported he was "not getting any better" but remained stable. Id. Diagnoses included GBS and end stage renal disease. Id. at 144.

Petitioner had a follow up examination for his diabetic retinopathy with Dr. Massey on February 26, 2018. Pet. Ex. 16 at 4. No changes in vision since petitioner's last visit were reported. Id. Dr. Massey found petitioner was in good condition and no treatment was needed at this time. Id. at 5. He recommended observation. Id. Dr. Massey noted that he first saw petitioner in 2012 and found petitioner's "eyes [were] significantly improved from 6 years ago." Id. at 27.

On April 10, 2018, petitioner visited Dr. Epperson for a follow up and evaluation for an electric scooter due to pain when walking a lot. Pet. Ex. 17 at 145. He was using a walker and a cane to ambulate, but reported low back pain and hip pain with prolonged walking. Id. at 146. Petitioner was still receiving two treatments of IVIG each month, and he was to continue to do so. Id. at 146, 150. Physical examination revealed decreased motor strength bilaterally in anterior tibialis and -5/5 intrinsic muscle of the hands, but was otherwise unchanged. Id. at 148. Dr. Epperson noted petitioner wore ankle braces for partial bilateral foot drop. Id. Impression remained GBS versus CIDP. Id. at 149. Dr. Epperson found petitioner met all criteria for an electric scooter and deemed it a medical necessity. Id. at 149, 151.

Petitioner returned to Ms. Adair at the Baptist Health Neurology Clinic on April 24, 2018 for a follow up regarding his obstructive sleep apnea. Pet. Ex. 27 at 85. He was receiving IVIG twice monthly and continued to experience numbness and weakness in his legs, hands, and feet. Id. At this visit, petitioner complained of "low back pain which radiates into both hips" that was "[w]orse after walking long distance[s] or after standing for prolonged period[s]." Id. He reported Dr. Epperson evaluated this pain and told petitioner it was due to age. Id. Physical examination revealed normal range of motion, moves all extremities well, 5/5 strength throughout, sensation decreased to vibration in stocking distribution bilaterally, symmetric reflexes, and steady gait with cane. Id. at 86. Petitioner wished to transfer his care to Baptist Health Neurology Clinic from Dr. Epperson and his records were requested. Id. Plan was to review records from Dr. Epperson regarding petitioner's GBS and low back pain. Id. at 86-87.

On August 2, 2018, petitioner returned to Ms. Adair at the Baptist Health Neurology Clinic. Pet. Ex. 27 at 183. He presented to transfer his care from Dr. Epperson to Dr. William Leuschke. Id. Petitioner reported developing paralysis from the waist down on October 1, 2012, which he "correlated [] to receiving his flu shot on [September 12, 2012]." Id. He stated he improved with IVIG, but his condition has not resolved. Id. He complained of continued numbness in his hips to feet bilaterally and balance difficulties. Id. He also reported an aching, pulling pain in his lower back that radiates into both hips and is "[w]orse after walking long distance[s] or after standing for prolonged period[s]" and has gotten worse over the past year. Id. He continues to receive two treatments of IVIG each month. Id. "Symptoms are complicated by previous diagnosis of diabetic neuropathy, [status post] amputation of great toe on right foot due to vascular disease, [C]harcot in right ankle, vs. CIDP." Id.

Physical examination revealed normal range of motion, moves all extremities well, 5/5 strength throughout except 4/5 in left anterior tibialis and 3+/5 in right anterior tibialis, sensation decreased to vibration in stocking distribution bilaterally, symmetric reflexes, and steady gait with cane. Pet. Ex. 27 at 184. Assessments were GBS, neuropathy, obstructive sleep apnea, and back pain. Id. at 184-85. Petitioner was ordered to continue IVIG twice each month and begin

physical therapy for balance and strength, and a lumbar spine computerized tomography ("CT") was ordered. Id. at 184. The CT documented a "disc bulge at L5-S1 and arthritis," as well as "[m]ild central stenosis at L4-5 and probably an old compression fracture at T11-12." Id. at 53.

Petitioner began physical therapy on August 29, 2018 to help with his back pain, pain with functional activities, fall and gait issues, balance problems, and difficulty changing and maintaining body position. Pet. Ex. 27 at 190-91. In a progress note dated October 1, 2018, petitioner reported his current problems have been present for six years after receiving a flu vaccine in 2012 and thereafter developing bilateral lower extremity weakness. Id. at 197. By October 1, 2018, petitioner continued to have problems with left lower back pain and bilateral lower extremity weakness but demonstrated improved movement pattern, improved strength in his trunk, and improved balance. Id. at 199.

On October 2, 2018, petitioner followed up with Ms. Adair at the Neurology Clinic for his GBS, back pain, and obstructive sleep apnea. Pet. Ex. 27 at 51. Physical examination was unchanged from his August 2018 visit. Id. at 52. Petitioner was ordered to continue with physical therapy and IVIG treatments. Id.

Petitioner was discharged from physical therapy on November 9, 2018. Pet. Ex. 27 at 208. His "movement patterns [were] much improved since his initial visit" and "treatment has progressed well." Id. at 209. He "continue[d] to have problems with [bilateral lower extremity] weakness and neuropathy. Id.

Petitioner returned to Dr. Epperson on October 10, 2018. Pet. Ex. 30 at 13. He continued to receive IVIG twice per month and reported he felt stable and felt "he [could not] do without IVIG." Id. He reported fatigue and "at times his legs feel heavy and feet [feel] numb." Id. Impression remained GBS versus CIDP. Id. at 16.

i. Medical History in 2019

Petitioner returned to the Neurology Clinic and saw Ms. Adair on April 15, 2019. Pet. Ex. 27 at 28. Petitioner reported his back pain improved with physical therapy and exercise. Id. He continued to have numbness in hips to feet bilaterally and balance difficulties. Id. He was receiving IVIG twice per month. Id. Physical examination was unchanged since the previous visit in October 2018. Id. at 29. Assessment remained obstructive sleep apnea, GBS, neuropathy, and back pain. Id. at 29-30. Ms. Adair ordered petitioner to continue with his IVIG treatment schedule and exercise, and she encouraged strict diabetic control for his neuropathy. Id.

On May 29, 2019, petitioner saw Dr. Epperson for a follow up on his "[GBS] versus CIDP." Pet. Ex. 30 at 20. Petitioner continued to receive IVIG twice monthly, and reported "doing well on the IVIG." Id. at 21. He complained of blurry and double vision in his left eye and reported he was referred to a specialist for possible muscle weakness behind his eye. Id. Physical examination revealed 3/5 strength bilaterally in anterior tibialis, 4/4 strength bilaterally in gastrocnemius, -5/5 strength in intrinsic muscle of hands, absent vibratory response lower extremities up to mid-thigh, altered sensation below T10 anteriorly, impaired proprioception

bilaterally in lower extremities, decreased sensation in a stocking glove distribution, gait that was broad and ataxic, lower extremity weakness, partial footdrop bilaterally, and absent deep tendon reflexes. Id. at 23. He walked with a cane and walker. Id. Dr. Epperson noted petitioner remained stabled on IVIG treatments twice monthly, and ordered him to continue with this treatment schedule. Id. at 24-25. Diagnoses included GBS, CIDP, and end stage renal disease. Id. at 26.

Dr. Epperson conducted an EMG/NCV on June 6, 2019 and found "electrophysiological evidence of a severe diffuse sensorimotor peripheral neuropathy compatible with GBS." Pet. Ex. 27 at 31. When compared to the previous studies from June 2017, "there [was] no improvement and minimal progression." Id.

On June 19, 2019, petitioner presented to ophthalmologist, Dr. Michal Vaphiades, for a new patient consultation. Pet. Ex. 36 at 3. Petitioner reported horizontal diplopia since May 10, 2019. Id. He stated he had this "in 2012 when he had bilateral optic nerve edema from GBS." Id. "The diplopia may be from the distortion in the left eye from [d]iabetic [r]etinopathy or another process like a vasculopathic cranial neuropathy." Id. Assessment was diplopia and gaze palsy. Id. at 9. Dr. Vaphiades believed he may have had a pontine stroke and contacted Dr. Epperson for a stroke work-up and computed tomography angiography ("CTA") of the head. Id. He also noted petitioner has optic nerve pallor which may have been from the previous optic nerve edema with GBS or previous [ischemic optic neuropathy]." Id. Brain CT was negative, and there were "no abrupt vessel occlusion, significant stenosis, or malformation." Pet. Ex. 38 at 4.

On October 22, 2019, petitioner returned to Ms. Adair at the Neurology Clinic for a follow up. Pet. Ex. 27 at 13. Since his last visit in April 2019, he reported concerns regarding his dose of IVIG because he felt it "was decreased in half" due to "worsened leg weakness and heaviness." Id. Physical examination was unchanged from the previous visit. Id. at 14. Assessment remained obstructive sleep apnea, back pain, GBS, and neuropathy. Id. at 14-15. Ms. Adair ordered petitioner to continue IVIG two days each month. Id. at 15.

On November 12, 2019, petitioner saw Dr. Philip H. Scharper for a follow up examination regarding his blurred and distorted vision. Pet. Ex. 35 at 3. Impression was proliferative diabetic retinopathy, epiretinal membrane, and nuclear sclerosis in both eyes, and his strabismus resolved. Id. at 5. He noted petitioner was stable and recommended observation. Id. He also discussed with importance of blood sugar control in preventing ocular complications. Id.

Petitioner returned to Dr. Epperson on November 21, 2019 for a follow up. Pet. Ex. 38 at 8. He reported he was doing "okay" since his last visit. Id. at 9. He stated his IVIG treatments were cut in half due to a shortage and "he is having a lot more weakness in his legs." Id. Dr. Epperson noted his left foot drop improved since his last visit, but his physical examination was otherwise unchanged. Id. at 11. Impression was GBS. Id. at 12. He stated petitioner may need to do IVIG two days every three weeks as long as his nephrologist approved. Id. at 14.

j. Medical History in 2020

On May 12, 2020, petitioner returned to Dr. Scharper for a follow up examination. Pet. Ex. 35 at 2. Dr. Scharper determined petitioner was stable and recommended observation. Id. at 3.

Petitioner returned to Dr. Epperson's office on June 18, 2020. Pet. Ex. 38 at 16. He stated he is receiving IVIG twice monthly but "that both of his legs are weak and feel like bricks." Id. Petitioner and his wife believed IVIG was "keeping him stable and want[ed] to continue the treatments." Id. Petitioner "report[ed] his symptoms have not improved, but have not worsened." Id. at 20. Physical examination revealed 5/5 motor strength throughout, intact sensory, good finger-to-nose and range of motion, and gait within normal limits. Id. at 18-19. Impression was GBS. Id. at 19. Petitioner returned on November 12, 2020. Id. at 21. Examination and records were unchanged. See id. at 21-26.

EMG/NCV conducted on November 12, 2020 found "evidence of a severe motor sensory peripheral neuropathy in the right lower extremity compatible with GBS" and "no electrophysiological evidence of a right L3-S1 radiculopathy." Pet. Ex. 38 at 5. There was no improvement from the last study in June 2019. Id.

No additional medical records were filed.

D. Petitioner's Affidavit

Prior to flu vaccination on September 12, 2012, his "medical history included diabetes for over 30 years (manages by insulin pump), coronary heart disease for which [he] received six or seven stents, and high blood pressure." Pet. Ex. 2 at 1.

On September 30, 2012, he "came home from work, showered, and sat down on the couch to watch television with [his] daughter." Pet. Ex. 2 at 1. When he stood up, "[his] legs were very wobbly and [he] almost fell down." Id. He woke up at 4:00 A.M. to go to work. Id. As he tried to stand up, he could not move or control his legs and he fell. Id. He went to the ER at Tallahassee Community Hospital, where he was prescribed pain medicine because the ER physicians believed he had a back problem. Id.

He continued to have no feeling in his legs and was incontinent when his primary care physician, Dr. Russell, referred him to a neurologist, Dr. Epperson, on October 2, 2012. Pet. Ex. 2 at 1-2. "By then, the paralysis that started in [his] legs had extended up to [his] abdomen." Id. at 2. On October 8, 2012, he returned to Dr. Epperson for an EMG/NCV study. Id. Dr. Epperson diagnosed him with GBS. Id. Dr. Epperson started petitioner on IVIG, and referred petitioner to specialist, Dr. Oh. Id.

He began to regain feeling in his legs, waist, and abdomen in October 2012. Pet. Ex. 2 at 2. When he saw Dr. Oh on February 5, 2013, he "had been able to walk with a cane or walker for about three weeks." Id.

As of March 12, 2018, the date he executed his affidavit, his condition since 2013 has remained the same. Pet. Ex. 2 at 2. He is able to walk, but usually needs to use a cane. Id. His legs and feet remain weak. Id. He also has numbness and balance problems. Id. He continues to see Dr. Epperson and receive IVIG. Id.

E. Dr. Epperson's Letter

On January 31, 2018,[21] Dr. Epperson wrote a letter to petitioner's counsel. Pet. Ex. 26 at 4. In the letter, Dr. Epperson summarized petitioner's presentation on October 2012 and noted "Dr. Oh agree[d] with the diagnosis of acute [GBS] and a T 10 transverse myelopathy." Id. He continued to treat petitioner throughout the years. Id. He opined that petitioner "developed acute [GBS] on [October 1, 2012] from the flu shot obtained [September 20, 2012].[22] This was documented by EMG/NCV testing and confirmed by Dr. Shin Oh, an authority on neuromuscular disease." Id.

F. Expert Reports

1. Petitioner's Expert, Dr. Shin J. Oh

a. Background and Qualifications

Dr. Oh is one of petitioner's treating physicians. He is board certified in neurology, electromyography, clinical neurophysiology, and neuromuscular disease. Pet. Ex. 28 at 1; Pet. Ex. 29 at 3. He received his M.D., Master's in Medical Science, and Ph.D. in Medicine from Seoul National University in Seoul, Korea. Pet. Ex. 29 at 2. He completed an internship, neurology residency, and an internal medicine residency in Seoul, Korea before completing a neurology residency at Georgetown University Hospital in Washington, DC. Id. Since 2014, he has been a Distinguished Professor Emeritus at the University of Alabama School of Medicine in Birmingham, Alabama. Id. at 1. Dr. Oh sits on various review boards and has authored or co-authored over 500 publications. Id. at 4-36.

b. Opinion

Dr. Oh opined that petitioner's "condition and diagnosis of GBS is consistent with the Table definition of GBS." Pet. Ex. 28 at 2. In his first report, Dr. Oh concluded that petitioner's proper diagnosis is AIDP and that his condition meets the Table definition set forth in Section 15(ii). Id. at 4. In his second report, he concluded that "[petitioner] developed GBS as GBS/ATM overlap syndrome," and that the flu vaccine "was more probably than not a substantial contributing cause of GBS." Pet. Ex. 32 at 2. In his third report, Dr. Oh opined petitioner's proper diagnosis is "atypical GBS," which meets the qualifications and aids to interpretation criteria in the Table. Pet. Ex. 39 at 4.

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[21] This letter is not dated but contains a stamp indicating it was faxed on January 31, 2018.

[22] Petitioner's correct date of vaccination is September 12, 2012. Pet. Ex. 1 at 4-7; Pet. Ex. 3 at 1.

Dr. Oh treated petitioner on February 5, 2013. Pet. Ex. 28 at 1. After performing a complete diagnostic work up, including consideration of petitioner's complex medical history, he concluded petitioner's "history and findings [] were typical of GBS, without evidence of recurrence, and which also included an atypical feature with T-10 sensory loss." Id. at 2. Dr. Oh's "diagnostic impression was atypical GBS with transverse myelopathy."[23] Id.

In his second report, Dr. Oh noted "[petitioner's] acute onset of bilateral flaccid limb weakness, loss of sensation in the lower extremities, areflexia, transient bladder dysfunction, monophasic pattern and nadir of motor weakness approximately 28 days after onset fits the clinical signs of GBS and acute [TM] (ATM) as GBS/ATM overlap syndrome." Pet. Ex. 32 at 1. Additionally, Dr. Oh found petitioner's CSF supportive of GBS and petitioner's EMG/NCV studies indicative of "a definite demyelinating neuropathy typical of GBS involving upper extremity and lower extremities." Id.

He opined that although transient bladder dysfunction and sensory loss below T-10 are atypical of GBS, they are common features of ATM. Pet. Ex. 32 at 1. Additionally, he found petitioner's atypical feature of bilateral optic neuropathy "could be a separate problem from acute onset neurological event in October or a continuing problem associated with GBS/ATM overlap syndrome as a spectrum of autoimmune disorder or neuromyelitis optica disorder." Id. at 1-2. In response to Dr. Donofrio's argument that GBS is an incorrect diagnosis because petitioner did not exhibit weakness in all four extremities, Dr. Oh noted that Asbury and Cornblath, cited by Dr. Donofrio, requires only "weakness of more than one limb," which petitioner demonstrated, and not weakness of all four extremities. Pet. Ex. 32 at 2 (quoting Resp. Ex. A, Tab 1 at 1); Pet. Ex. 39 at 1-2.

Dr. Oh cited Guo and Zhang[24] and Oliveira et al.,[25] which both discuss GBS/TM overlap syndrome. Pet. Ex. 32 at 1. Guo and Zhang examined 23 cases[26] and "concluded that GBS/ATM overlap syndrome should be suspected in patients (1) with signs of areflexia or hyporeflexia and with positive pyramidal signs, (2) who suffered pain at the onset of the disease." Pet. Ex. 33 at 2, 4. "Symptom observation showed that sensory level and sphincter disturbance indicate concurrent ATM, as well as an abnormal spinal cord [MRI] detected in

[23] The reason for Dr. Oh's use of the words "typical" and "atypical" GBS, which seem inconsistent, is unclear.

[24] Fang Guo & Yong-Bo Zhang, Clinical Features and Prognosis of Patients with Guillain-Barré and Acute Transverse Myelitis Overlap Syndrome, 181 Clinical Neurology & Neuroscience 127 (2019).

[25] L. M. Oliveira et al., Concomitant Transverse Myelitis and Acute Axonal Sensory-Motor Neuropathy in an Elderly Patient, 2017 Case Reps. Immunology 1.

[26] The authors excluded "patients with polyneuropathy that was cause by a . . . endocrine disorder," such as diabetes. Pet. Ex. 33 at 2.

almost all patients with GBS/ATM overlap syndrome."[27] Id. at 4. One of the cases examined by Guo and Zhang was discussed in Oliveira et al. Oliveira et al. reported AMSAN[28] and TM in a 64-year-old male. Pet. Ex. 34 at 1. The patient received a flu vaccine, and five days later developed a productive cough and diarrhea lasting three days. Id. Thirteen days later, or 18 days after vaccination, he "presented to the [ED] with a one-day history of lower extremities distal numbness, rapidly progressing to four-limb weakness, back pain, dysarthria, facial weakness, and diplopia." Id. Both Guo and Zhang and Oliveira et al. noted the diagnostic challenge with GBS/TM overlap syndrome. Id. at 1; Pet. Ex. 32 at 5.

Next, Dr. Oh opined petitioner meets the interval between onset and nadir of symptoms. Pet. Ex. 28 at 2. He found petitioner's symptom onset was October 1, 2012. Id. Petitioner was in a wheelchair between October 23 and October 26, 2012, and by October 30, after receiving IVIG treatment, petitioner exhibited improvement. Id. Even though petitioner's October 2012 records note reports back pain for the few weeks before the onset of his numbness, Dr. Oh opined that the back pain was unrelated to petitioner's GBS and the sudden numbness was consistent with GBS. Id. at 3-4.

Dr. Oh found no evidence of a "significant relapse" in petitioner's clinical course. Pet. Ex. 28 at 2. Although petitioner received IVIG intermittently, and statements in his medical records indicate his leg weakness was improving but ongoing, Dr. Oh opined that these facts do not constitute evidence of a significant relapse. Id. He explained that while petitioner's symptoms fluctuate, they are "distinguishable clinically from recurring or a new onset neurological condition because they are not considered a significant or marked deterioration." Pet. Ex. 39 at 1. Looking at all of the records together, Dr. Oh opined there is "a consistent clinical presentation of symptoms [petitioner] had been experiencing for several years, and not an objectively demonstrated significant change or deterioration." Id. Dr. Oh found petitioner's condition stabilized and "[t]here is no documentation by any objective neurological evaluations, evidence of hospitalizations, or objective manual muscle strength evaluations demonstrating significant relapse." Pet. Ex. 28 at 2.

With regard to alternative diagnoses, Dr. Oh maintained there is nothing in petitioner's records to suggest a more likely alternative diagnosis. Pet. Ex. 32 at 2. Dr. Oh opined that "[petitioner's] ATM is an overlapping syndrome and does not exclude GBS as the correct primary diagnosis and a substantial contributing cause of his residual weakness." Id. Dr. Oh ruled out CIDP because he found no evidence of a significant relapse by any objective evaluation. Pet. Ex. 28 at 2-3.

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[27] Petitioner's MRI did not show an abnormal spinal cord, or any lesion described as consistent with TM. See Pet. Ex. 4 at 88-89.

[28] AMSAN is "a rare subtype of [GBS] involving primarily large sensory nerve fibers in the limbs, with paresthesias and weakness but not paralysis." Acute Motor-Sensory Axonal Neuropathy, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=92652 (last Jan. 31, 2022). AMSAN is one of the four subtypes of GBS that meets the Vaccine Table criteria.

Additionally, Dr. Oh found it unlikely that petitioner had MS because (1) it was ruled out with diagnostic testing, and (2) petitioner had abnormal NCV findings atypical in patients with MS. Pet. Ex. 32 at 1-2. In response to Dr. Donofrio's opinion that petitioner's MRI findings were consistent with a demyelinating disease such as MS, Dr. Oh explained that petitioner's 20 plus-year history of diabetes and hypertension accounted for the MRI findings and "is a more likely explanation than MS." Pet. Ex. 39 at 3. Additionally, petitioner did not have oligoclonal bands when tested in January 2013, which are found in approximately 70% of MS patients. Id. at 3-4; see also Pet. Ex. 41.

2. Respondent's Expert, Dr. Peter D. Donofrio

a. Background and Qualifications

Dr. Donofrio is board certified in neurology, internal medicine, electrodiagnostic medicine, and neuromuscular medicine. Resp. Ex. B at 2. After receiving his M.D. from Ohio State University School of Medicine, he completed residencies in internal medicine and neurology and a neuromuscular fellowship. Id. at 1-2. At the time Dr. Donofrio provided his opinions, he was a Professor of Neurology at Vanderbilt University Medical Center and Chief of the Neuromuscular Section and Director of the EMG lab. Resp. Ex. A at 1. He has experience in evaluating various neuropathies, including GBS and CIDP, and has published on those areas. Id. He also has experience reviewing literature and data regarding vaccine-related GBS, CIDP, TM, MS, and other neurologic conditions. Id. Dr. Donofrio has held various academic, hospital, and medical school appointments, and has authored or co-authored over 200 publications. Resp. Ex. B at 2-8, 13-31.

b. Opinion

Dr. Donofrio opined petitioner does not meet the criteria for GBS and/or TM, and instead, his presentation best fits the diagnosis of MS. Resp. Ex. A at 7-9; Resp. Ex. C at 3-4. He explained that petitioner does not have GBS because (1) he did not have weakness in his upper extremities, (2) he had bladder incontinence at onset, (3) he has received IVIG since 2012, and (4) his EMG/NCV studies were consistent with a severe advanced diabetic polyneuropathy. Resp. Ex. A at 7-9; Resp. Ex. C at 1-4.

For additional support of his opinion that petitioner did not have GBS because he did not have weakness in his upper extremities, Dr. Donofrio cited to Dr. Epperson's records from October 2, 2012, where Dr. Epperson "rule[d] out [GBS] since weakness [was] confined to the lower extremities and not ascending to upper extremities." Resp. Ex. A at 7 (quoting Pet. Ex. 4 at 14). Dr. Donofrio also cited Asbury and Cornblath to explain that GBS patients "typically have weakness in both legs and upper extremities and have either hyperreflexia or areflexia in four limbs within a few days of disease presentation," which he opined petitioner did not meet. Id. (citing Resp. Ex. A, Tab 1 at 1).

According to Asbury and Cornblath, "[t]wo features [] required for the diagnosis of GBS [are] progressive motor weakness and areflexia." Resp. Ex. A, Tab 1 at 2. "Motor weakness must occur in more than one limb" and "[t]he degree ranges from minimal weakness of the legs,

with or without ataxia, to total paralysis of the muscles of all four extremities." Id. at 1-2. Areflexia, or loss of tendon reflexes, may mean "some reflexes are lost, usually distally and symmetrically, and others are hypoactive, generally the more proximal ones." Id. at 2. The authors further noted that weakness may precede areflexia "usually by not more than two or three days, in the early phases of the illness." Id.

Dr. Donofrio also opined that "bladder and bowel involvement early in an illness rules out the diagnosis of GBS." Resp. Ex. A at 7. Here, petitioner lost bladder control and developed constipation on October 1, 2012, the same day he presented with sudden onset of numbness. Id. Asbury and Cornblath note "[p]ersistent bladder or bowel dysfunction" and "[b]ladder or bowel dysfunction at onset" cast doubt on a diagnosis of GBS. Resp. Ex. A, Tab 1 at 2. However, the authors also state that variant factors, like transient bladder paralysis, "do[] not rule out the diagnosis of GBS but should raise doubts. The presence of two variant features compound suspicions that the diagnosis of GBS is incorrect." Id. Dr. Donofrio argued that "abrupt onset of leg weakness and bladder and bowel dysfunction without upper limb involvement suggests spinal cord disease and would be much more commonly observed in [TM] or [MS]." Resp. Ex. A at 7.

Dr. Donofrio noted that petitioner has received IVIG on-and-off since 2012. Resp. Ex. A at 8. He opined that he is not certain why IVIG since 2012 was indicated. Id. According to Dr. Donofrio, "IVIG is never used chronically in the treatment of GBS and its continued use suggest[s] another disorder. Chronic use of IVIG is prescribed in the management of patients with CIDP who do not respond to steroids or plasma exchange." Id. at 9; see also Resp. Ex. C at 2; Resp. Ex. A, Tab 4 at 4-5.[29] Additionally, petitioner's medical records document improvement following IVIG treatment over the years. Resp. Ex. A at 9. Such improvement "would not be expected in GBS, a monophasic illness that usually improves by four weeks after the onset of symptoms." Id. Lastly, because petitioner received IVIG since 2012, Dr. Donofrio argued petitioner has not yet reached his nadir of symptoms. Resp. Ex. C at 1-2.

Although all EMG/NCV tests were interpreted as consistent with GBS, Dr. Donofrio opined the results can also been seen in a severe diabetic polyneuropathy. Resp. Ex. A at 8; Resp. Ex. C at 2. According to Bowley and Chad,[30] "electrophysiologic and pathologic features attributed to demyelination are well reported" in diabetic polyneuropathy and "[n]erve conduction abnormalities are dependent on the degree of glycemic control." Resp. Ex. C, Tab 4 at 19. Because of petitioner's long-standing diabetes and neuropathy diagnosis in 2010, Dr. Donofrio believed chronic denervation on needle examination should be found. Resp. Ex. A at 8.

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[29] Joint Task Force of the EFNS and the PNS, European Federation of Neurological Societies/Peripheral Nerve Society Guideline on Management of Chronic Inflammatory Demyelinating Polyradiculoneuropathy: Report of a Joint Task Force of the European Federation of Neurological Societies and the Peripheral Nerve Society - First Revision, 15 J. Peripheral Nervous Sys. 1 (2010).

[30] Michael P. Bowley & David A. Chad, Clinical Neurophysiology of Demyelinating Polyneuropathy, 161 Handbook Clinical Neurology 242 (2019).

Dr. Donofrio also explained that petitioner does not meet the diagnostic criteria for TM, and his treating neurologist, Dr. Epperson did not diagnose petitioner with TM. Resp. Ex. C at 3; see Resp. Ex. A, Tab 2 (proposing diagnostic criteria for ATM).[31] Dr. Donofrio explained that petitioner did not meet the criteria for TM because (1) petitioner did not have inflammation in the spinal fluid or abnormalities on MRI of the spinal cord, and (2) petitioner did not reach nadir within 21 days of disease onset. Resp. Ex. C at 3. Additionally, Dr. Donofrio opined petitioner's presentation included exclusionary criteria for TM, including MRI features suggestive of MS and an episode of clinically apparent optic neuritis. Id.

Dr. Donofrio opined petitioner's presentation is strongly suggestive of MS, presenting as a thoracic myelopathy and optic neuritis, because (1) petitioner developed sudden onset of lower extremity weakness and bowel and bladder dysfunction; (2) petitioner's brain MRI was consistent with a demyelinating disease; and (3) "petitioner had visual evoked potentials that showed dysfunction of the bilateral visual pathway," consistent with central nervous system demyelinating diseases. Resp. Ex. A at 8-9; see also Resp. Ex. C at 2, 4. He added that changes depicted on petitioner's MRI and visual evoked potentials would not be expected in patients with GBS or CIDP. Resp. Ex. A at 8. Dr. Donofrio concluded that "[t]he brain MRI abnormalities, the elevated oligoclonal banding,[32] the spinal cord dysfunction by clinical examination, and the abnormal visual evoked responses would meet the revised McDonald criteria for [MS]."[33] Id. He acknowledged further testing would be required to substantiate a diagnosis of MS or another demyelinating disorder in petitioner because he suffers from diabetic neuropathy. Id. at 9.

Next, Dr. Donofrio discussed some of petitioner's symptoms and findings on presentation to further support his opinion that petitioner did not develop GBS. Because petitioner had normal upper extremity reflexes, Dr. Donofrio opined that this "would rule out the diagnosis of GBS and would be highly unusual in CIDP." Resp. Ex. A at 8. Petitioner's scotomata in both eyes is also "consistent with a demyelinating disease of the optic nerve, highly suggestive of [MS], and not expected in GBS or CIDP." Id. He opined that petitioner had uncontrolled diabetes and diabetes is a common cause of an elevated protein level in the CSF. Id.; Resp. Ex. C at 2; see also Resp. Ex. C, Tab 3 at 2 (noting two studies that found 68% and 72% of patients with diabetic neuropathy had an elevated CSF protein level).[34] Additionally, elevated protein levels, according to Dr. Donofrio, can be seen in MS patients. Resp. Ex. A at 8. Lastly, he noted that petitioner's lower back pain three weeks before onset of his lower extremity weakness "suggests either a mechanical or musculoskeletal cause for the low back pain," or "acute onset of a demyelinating disease or spinal cord infarct in the midthoracic region." Id. at 9.

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[31] Transverse Myelitis Consortium Working Group, Proposed Diagnostic Criteria and Nosology of Acute Transverse Myelitis, 59 Neurology 499 (2002).

[32] Petitioner did not have elevated oligoclonal bands. Pet. Ex. 12 at 25.

[33] Dr. Donofrio did not cite to the most updated McDonald criteria. Compare Resp. Ex. A, Tab 3, with Pet. Ex. 41.

[34] Robert A. Fishman, Cerebrospinal Fluid in Diseases of the Nervous System 317 (1980).

III. LEGAL STANDARDS

A. Standards for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" Rooks v. Sec'y of Health & Hum. Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

To receive compensation through the Program, petitioner must prove either (1) that petitioner suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that he received, or (2) that petitioner suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Here, petitioner primarily seeks to establish a Table claim, and he therefore must make a factual showing sufficient to meet the Table's relevant definitions, as set forth in the Table's Qualifications and Aids to Interpretation. § 14(b).

Petitioner's burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). A petitioner who satisfies this burden is entitled to compensation unless respondent can prove, by a preponderance of the evidence, that the vaccinee's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B).

B. Factual Issues

A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding his claim. § 13(a)(1)(A). To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See Burns v. Sec'y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records).

Medical records generally "warrant consideration as trustworthy evidence." Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). However, greater weight is typically given to contemporaneous records. Vergara v. Sec'y of Health & Hum. Servs., No. 08-882V, 2014 WL 2795491, at *4 (Fed. Cl. Spec. Mstr. May 15, 2014) ("Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recorded in later medical histories, affidavits, or trial testimony."). Contemporaneous medical records are presumed to be accurate. See Cucuras, 993 F.2d at 1528. The weight afforded to

contemporaneous records is due to the fact that they "contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium." Id. To overcome the presumptive accuracy of medical records, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." Sanchez v. Sec'y of Health & Hum. Servs., No. 11-685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing Blutstein v. Sec'y of Health & Hum. Servs., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)), mot. for rev. denied, 142 Fed. Cl. 247 (2019), vacated on other grounds & remanded, 809 F. App'x 843 (Fed Cir. 2020).

There are situations in which compelling testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. Campbell v. Sec'y of Health & Hum. Servs., 69 Fed. Cl. 775, 779 (2006) ("[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."); Lowrie v. Sec'y of Health & Hum. Servs., No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) ("[W]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." (quoting Murphy v. Sec'y of Health & Hum. Servs., 23 Cl. Ct. 726, 733 (1991), aff'd per curiam, 968 F.2d 1226 (Fed. Cir. 1992))). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley v. Sec'y of Health & Hum. Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

Despite the weight afforded medical records, special masters are not bound rigidly by those records in determining onset of a petitioner's symptoms. Valenzuela v. Sec'y of Health & Hum. Servs., No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); see also Eng v. Sec'y of Health & Hum. Servs., No. 90-1754V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb. 18, 1994) (Section 13(b)(2) "must be construed so as to give effect also to § 13(b)(1) which directs the special master or court to consider the medical records (reports, diagnosis, conclusions, medical judgment, test reports, etc.), but does not require the special master or court to be bound by them").

C. Lookback Provision

The statutory deadlines for filing petitions under the Vaccine Act are set forth at § 16. Under the Vaccine Act, a person "who has sustained a vaccine-related injury" must file a claim within 36 months of the onset of the symptoms of the injury. § 16(a)(2). This period can be extended under § 16(b) of the Vaccine Act, which provides that "any time the Vaccine Injury Table is revised and the effect of such revision is to permit an individual who was not, before such revision, eligible to seek compensation under the Program, or to significantly increase the likelihood of obtaining compensation, such person may . . . file a petition for such compensation not later than [two] years after the effective date of the revision" provided the vaccine-related

injury occurred within eight years before the date of the revision of the Table (March 21, 2017).[35]

Section 16(b) is triggered "only if (1) eligibility is new or (2) eligibility is 'significantly increase[d].'" O'Connell v. Sec'y of Health & Hum. Servs., 63 Fed. Cl. 49, 60 n.9 (2004); see also Gorski v. Sec'y of Health & Hum. Servs., No. 97-156V, 1997 WL 739497, at *5 (Fed. Cl. Spec. Mstr. Nov. 13, 1997). The first application, where eligibility is new, "has been held to apply when a new vaccine is added to the table thereby creating eligibility for Program compensation." Simpson v. Sec'y of Health & Hum. Servs., No. 17-944V, 2019 WL 11815360, at *4 (Fed. Cl. Spec. Mstr. Aug. 7, 2019). The second application, when eligibility is "significantly increase[d]," "has been held to apply when a new vaccine injury is added to the Table." Id.

The phrase "significantly increase the likelihood of obtaining compensation" is not defined in the Vaccine Act. § 16(b); see also § 33 (general provision of the Vaccine Act that defines certain words). Although nonbinding, special masters have provided various interpretations of the § 16(b) look-back provision. See, e.g., K.G. v. Sec'y of Health & Hum. Servs., No. 18-120V, 2018 WL 5795834, at *12 (Fed. Cl. Spec. Mstr. Aug. 17, 2018); Muchnick v. Sec'y of Health & Hum. Servs., No. 97-89V, 1998 WL 1012801, at *7 (Fed. Cl. Spec. Mstr. July 15, 1998); Gorski, 1997 WL 739497, at *4-5.

The petitioner in Gorski, filed a petition alleging a Table claim of measles-mumps-rubella ("MMR") and arthritis. Gorski, 1997 WL 739497, at *1. The special master found that because the Table revision only added a Table claim for a defined injury, the petitioner was not now, for the first time, "eligible" to assert such a claim because petitioner was already "eligible" to file a non-Table claim prior to the revision. Id. at *5. The special master also found that while it could be argued that adding a Table claim might "add[] credence to the general theory" that the vaccine can cause that injury, the Table revision did not affect an allegation that the vaccine actually caused an injury, and thus did not "significantly increase [petitioner's] likelihood of obtaining compensation." Id.

More recent Program cases have addressed whether the lookback provision applies to facially-deficient flu-GBS Table claims. In Simpson, the undersigned found § 16(b) applies to petitioner's non-table GBS claim because the revision "significantly increase[d]" petitioner's claim. Simpson, 2019 WL 11815360, at *6-7. The undersigned relied on the volume of causation-in-fact flu-GBS cases compensated in the program following the March 2017 Table revision adding GBS to the Table, and the fact that petitioner's injury was consistent with GBS, with a 47-day onset, five days outside the Table definition. Id. However, in K.G., another GBS case following the March 2017 Table revision, the special master determined that the look-back provision did not apply. K.G., 2018 WL 5795834, at *12. The special master found petitioner's

[35] The Vaccine Table was revised and effective on March 21, 2017 to include GBS as a Table injury following administration of the seasonal flu vaccine. National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 82 Fed. Reg. 6294, 6295 (Jan. 19, 2017); National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table; Delay of Effective Date, 82 Fed. Reg. 11321, 11321 (Feb. 22, 2017).

four-month onset of GBS post-vaccination was "wholly inconsistent with GBS" because the onset period was "too long outside the 42-day window to successfully establish a Table injury." Id.

Section 16(b) "is not a jurisdictional life-preserver for all claimants; it allows a petitioner additional time to file only when the substantive law is changed in his favor." O'Connell, 63 Fed. Cl. at 60 n.9 (citing Gorski, 1997 WL 739497, at *4 ("[B]ecause the Vaccine Injury Table was in fact revised to include a new 'Table Injury' . . . the possibility is raised that petitioner could benefit from the added filing period provided in 300aa–16(b)."); Snawder v. Cohen, 749 F. Supp. 1473, 1477 n.4 (W.D. Ky. 1990) (noting this provision may be triggered "if the Vaccine Injury Table is revised to make vaccine-related injuries which were not formerly compensable eligible for compensation").

IV. ANALYSIS

After a review of the entire record, including the medical records, expert reports, and parties' briefs, in accordance with the applicable legal standards, the undersigned finds GBS to be the petitioner's appropriate diagnosis. Additionally, the undersigned finds petitioner has proven by preponderant evidence that he meets the Table criteria for GBS following flu vaccination, and is thus, entitled to compensation. The undersigned's Ruling is based on the following reasons.

A. Petitioner's Treating Physicians Diagnosed Him with GBS

On the morning of October 1, 2012, petitioner presented to the ER complaining of lower back pain that started three weeks before after twisting, and leg numbness that began that day. Petitioner was diagnosed with a lumbar strain. Later that day, he presented to his primary care physician, Dr. Russell reporting a "sudden onset of numbness from his waist down" and difficulty walking. Pet. Ex. 24 at 13. Assessment was lumbago and peripheral neuropathy, but Dr. Russell referred him to a neurologist to ensure petitioner did not have TM.

On October 2, 2012, petitioner saw neurologist, Dr. Epperson, for "sudden flaccid weakness and altered sensation below the waist which has continued for 24 hours." Pet. Ex. 4 at 9. Dr. Epperson thought petitioner could be suffering from a spinal cord compression and/or spinal cord infarction, and ordered MRIs and MRAs of the lumbar and thoracic spines. He believed GBS could be ruled out "since weakness [was] confined to the lower extremities and not ascending to upper extremities." Id. at 14.

However, on October 8, 2012, petitioner's EMG/NCV studies showed a severe diffuse sensorimotor peripheral neuropathy in the left and right lower extremity and right upper extremity compatible with GBS. Dr. Epperson's impression was "severe diffuse neuropathy in the lower extremities and right upper extremity compatible with [GBS] versus a severe neuropathy from diabetes." Pet. Ex. 4 at 18. A lumbar puncture was ordered, and petitioner was referred to neuromuscular specialist, Dr. Oh. On February 5, 2013, petitioner saw Dr. Oh, whose diagnostic impression was atypical GBS with transverse myelopathy.

On October 15, 2012, a lumbar puncture was conducted. Petitioner's CSF revealed elevated protein of 75. On October 22, 2012, petitioner saw Dr. Thompson for IVIG treatment. Dr. Thompson's diagnosis was "[a]cute onset [GBS] with paralysis up to T10." Pet. Ex. 6 at 32. For the remainder of 2012, petitioner's diagnosis remained GBS.

In 2013, Dr. Thompson's diagnosis remained GBS. Dr. Epperson's diagnosis remained "severe diffuse neuropathy in the lower extremities and right upper extremity compatible with [GBS] versus a severe neuropathy from diabetes." Pet. Ex. 4 at 22. Dr. Epperson noted that although the December 2012 MRI could not exclude a demyelinating disease, his MS profile was negative. Thus, diagnostic testing for MS was performed, and MS was ruled out.

In January 2014, Dr. Epperson's findings were "compatible with GBS and not diabetic neuropathy." Pet. Ex. 4 at 33. Throughout 2014, Dr. Epperson's diagnoses of petitioner remained GBS. From 2015 to 2017, Dr. Epperson's diagnoses included GBS, acute infective polyneuritis, chronic inflammatory demyelinating polyneuritis, and polyneuropathy in diabetes. In 2018, Dr. Epperson's diagnoses included GBS, and his impression was GBS versus CIDP. In 2018, petitioner began visiting the Baptist Health Neurology Clinic. Petitioner's diagnoses in 2018 and 2019 were GBS and neuropathy. In May 2019, petitioner returned to Dr. Epperson. Dr. Epperson's diagnoses included GBS and CIDP. In November 2019, Dr. Epperson's impression was GBS. Dr. Epperson's diagnosis remained GBS in 2020.

From 2014 through 2019, petitioner's neurologist Dr. Epperson's diagnosis continued to be GBS, although he also referenced CIDP. However, these references to CIDP are inconsistent. In 2018, Dr. Epperson questioned whether petitioner could have GBS versus CIDP. This indicated Dr. Epperson questioned the diagnosis of CIDP. The fact that Dr. Epperson questioned the diagnosis, however, suggests uncertainty. In 2018, when petitioner was seen at a different neurology clinic, petitioner's diagnosis was GBS and not CIDP. When petitioner returned to see Dr. Epperson in November 2019, Dr. Epperson's diagnosis was GBS. And in 2020, Dr. Epperson's diagnosis remained GBS.

After a review of the medical records, the undersigned finds that once petitioner underwent diagnostic testing, his treating neurologist consistently diagnosed petitioner with GBS. Although CIDP and other neuropathies were sometimes included in petitioner's medical records, those conditions were only ever listed as differential diagnoses.

In comparison, none of petitioner's treating neurologists ever diagnosed MS. Dr. Epperson performed an evaluation in 2012 that included a thoracic spine MRI. The study did not show any lesions that were interpreted as suggestive for TM or MS. Brain MRI did show multifocal areas of abnormality, but petitioner's diabetes was noted to account for the finding. Further, petitioner's treating neurologists did not attribute the abnormalities on the brain MRI to be due to MS. Lastly, oligoclonal bands were negative.

B. Petitioner's Onset Is Between Three and 42 Days Post-Vaccination

For a flu-GBS Table claim, the initial manifestation must be between three and 42 days after vaccination. 42 C.F.R. § 100.3(a)(XIV)(D). There is no dispute that petitioner received the

flu vaccine at issue on September 12, 2012. Petitioner averred he developed weakness the night of September 30, 2012. Dr. Oh and Dr. Donofrio agree petitioner's weakness began on October 1, 2012. This places petitioner's onset 18 or 19 days after vaccination. Therefore, onset falls squarely within the Table definition for GBS for the flu vaccine.

C. Petitioner Meets the Qualifications and Aids to Interpretation for a Table GBS Claim

Under the Vaccine Table Qualifications and Aids to Interpretation, the following five criteria must be met for diagnosis of GBS:

> (A) Bilateral flaccid limb weakness and decreased or absent deep tendon reflexes in weak limbs;
> (B) A monophasic illness pattern;
> (C) An interval between onset and nadir of weakness between 12 hours and 28 days;
> (D) Subsequent clinical plateau (the clinical plateau leads to either stabilization at the nadir of symptoms, or subsequent improvement without significant relapse; however, death may occur without a clinical plateau); and,
> (E) The absence of an identified more likely alternative diagnosis.

42 C.F.R. § 100.3(c)(15)(ii). Supportive, but not required, evidence of a GBS diagnosis "includes electrophysiologic findings consistent with GBS or an elevation of [CSF] protein with a total CSF white blood cell count below 50 cells per microliter." Id. at § 100.3(c)(15)(iv).

"To qualify as any subtype of GBS, there must not be a more likely alternative diagnosis for the weakness." 42 C.F.R. § 100.3(c)(15)(v). Exclusionary criteria for the diagnosis of GBS include, but are not limited to, the ultimate diagnosis of CIDP, spinal cord infarct, spinal cord compression, subacute inflammatory demyelinating polyradiculoneuropathy, MS, and more. Id. at § 100.3(c)(15)(vi).

A review of the medical records shows that petitioner has established that he meets these criteria. Further, petitioner's expert, Dr. Oh, provides persuasive evidence that petitioner has met these criteria.

1. Bilateral Flaccid Limb Weakness and Decreased or Absent Deep Tendon Reflexes in Weak Limbs

On October 1, 2012, petitioner reported sudden onset numbness from the waist down and difficulty walking. Physical examination revealed "[v]ery positive leg raising bilaterally with subjective numbness from his waist down." Pet. Ex. 24 at 14. On October 2, 2012, Dr. Epperson's physical examination revealed lower extremity weakness. Dr. Epperson's impression was "[s]udden onset flaccid paralysis." Pet. Ex. 4 at 14. On October 22, 2012, Dr. Thompson saw petitioner and his physical examination revealed "profound weakness up to T-10." Pet. Ex. 6 at 31.

Regarding decreased deep tendon reflexes, the undersigned finds that criterion met, as evidenced by Dr. Oh's physical examination on February 5, 2013. He found decreased reflexes in petitioner's ankles. Pet. Ex. 5 at 2. Previous examination by Dr. Epperson, however, did not show decreased reflexes at the ankles. For example, on February 4, 2013, Dr. Epperson charted normal deep tendon reflexes. Pet. Ex. 4 at 21. The next day, Dr. Oh charted decreased reflexes at the ankles. Pet. Ex. 5 at 2. Thus, two physical examinations separated by 24 hours are inconsistent. The undersigned finds Dr. Oh's note to be more accurate and reliable for several reasons. First, Dr. Oh is a specialist and Dr. Epperson referred petitioner to Dr. Oh for his special expertise. Second, Dr Oh's notes are more detailed and specific, evidencing a more thorough examination. Lastly, Dr. Epperson's examinations appear almost identical, if not identical, to his first examination on October 2, 2012. Thus, a review of petitioner's medical records shows that he had bilateral flaccid limb weakness and decreased reflexes.

Dr. Oh opined that petitioner demonstrated "bilateral flaccid limb weakness, loss of sensation in the lower extremities, [and] areflexia." Pet. Ex. 32 at 1. Dr. Oh's opinions appear to be derived from his physical examination in February 2013.

Dr. Donofrio opined petitioner did not have GBS because he did not have weakness and either hyperreflexia or areflexia in his upper extremities. However, the Table criteria do not require weakness and areflexia in all four limbs. Dr. Donofrio is applying additional criteria, exceeding what is set forth in the Table.

Petitioner's treating physicians consistently note weakness in both lower extremities, meeting the bilateral flaccid limb weakness requirement. Additionally, petitioner exhibited decreased or absent deep tendon reflexes on Dr. Oh's examination, also meeting this requirement. Thus, the undersigned finds this criterion met.

2. A Monophasic Illness Pattern

According to the most contemporaneous-in-time records and petitioner's reports, petitioner experienced onset of leg numbness and weakness some time shortly before October 1, 2012. On October 1, 2012, petitioner could barely walk, and was using an umbrella as a cane. By October 8, 2012, petitioner reported his numbness had increased and Dr. Epperson noted petitioner was disabled. By October 22, 2012, petitioner was in a wheelchair. He received IVIG from October 23 to October 26, 2012. At a follow up examination on October 30, 2012, petitioner was able to move his leg and foot much better and he was able to ambulate with crutches. Since then, his treating physicians note petitioner continues to experience residual weakness. However, none of his treating physicians document any significant deterioration in symptoms or concerns that petitioner experienced any significant relapse.

Dr. Donofrio argued improvement after IVIG over the years would not be expected in a monophasic illness like GBS. In contrast, Dr. Oh explained petitioner's symptoms have fluctuated some over the years, but those fluctuations represented "a consistent clinical presentation of symptoms" clinically distinguishable from a significant relapse. Pet. Ex. 39 at 1.

After a review of the medical records and experts' reports, the undersigned finds petitioner's illness was monophasic. Petitioner's symptoms stabilized after his first round of IVIG in October 2012, and since then, he has not experienced a significant deterioration of symptoms or had a significant relapse. Petitioner has residual symptoms from his GBS, that appear to be sequelae of his GBS. As described in more detail below, the undersigned finds petitioner's condition plateaued. Thus, petitioner has met this criterion.

3. An Interval Between Onset and Nadir of Weakness Between 12 Hours and 28 Days

As noted above, petitioner's onset was 18 or 19 days after vaccination, around September 30, 2012 to October 1, 2012. Petitioner reported weakness of his legs on October 1, 2012, and he was in a wheelchair by October 22, 2012. The undersigned finds petitioner reached his nadir of weakness on approximately October 22, 2012. This timeframe between onset and nadir is 21 days, which is between the 12 hour and 28 day requirement, and thus, petitioner has met this criterion.

4. Subsequent Clinical Plateau Leading to Stabilization at the Nadir of Symptoms or Subsequent Improvement Without Significant Relapse

The undersigned also finds this criterion met. As stated above, the undersigned found petitioner's nadir of weakness to be on or around October 22, 2012 when petitioner could no longer ambulate and had to use a wheelchair. Petitioner underwent his first round of IVIG that week. At a visit on October 30, 2012, petitioner was able to ambulate with crutches. Subsequently, he was able to walk without crutches. By December 2012, Dr. Thompson noted petitioner engaged in normal activity with effort. The undersigned finds petitioner reached a clinical plateau.

Since then, he has periodically used a cane to ambulate, and continues to experience residual weakness. Petitioner has continually reported the feeling of heavy, weak legs before IVIG treatments, and improvement after IVIG treatments. His treating physicians confirmed he continued to experience leg weakness, but noted his symptoms improved within IVIG treatments.

Dr. Oh acknowledged that petitioner's symptoms fluctuated, but opined petitioner's symptoms represent "a consistent clinical presentation of symptoms [petitioner] had been experiencing for several years." Pet. Ex. 39 at 1. He found petitioner's symptoms to be clinically distinguishable from a recurring or a new onset neurological condition, and found they did not demonstrate significant relapse.

After a review of the medical records and experts' reports, the undersigned finds that petitioner had subsequent improvement without significant relapse. After petitioner's first round of IVIG in October 2012, he was able to ambulate with crutches, and no longer requires a wheelchair. Since then, he has periodically required a cane to ambulate, but has not required use of a wheelchair. Thus, the undersigned finds no evidence of a significant relapse. None of petitioner's treating physicians related petitioner's continued symptom of leg weakness to a

relapse in symptoms. His residual symptoms experienced since 2012, which his treating physicians treat with IVIG, are sequela of his GBS.

5. The Absence of An Identified More Likely Alternative Diagnosis

Respondent's expert, Dr. Donofrio, opined petitioner's presentation most likely fits MS. He concluded petitioner met the McDonald criteria of MS because he had brain MRI abnormalities, elevated oligoclonal banding, spinal cord dysfunction by clinical examination, and abnormal visual evoked responses. However, he acknowledged further testing would be required to substantiate a diagnosis of MS.

There are a few issues with Dr. Donofrio's opinions. First, petitioner's MRI did not support a diagnosis of MS specifically. The brain MRI impression was "multifocal areas of signal abnormality within portion of the white matter of both hemispheres," which was "somewhat greater than expected for the age of the patient." Id. at 30. The radiologist "[could not] exclude a demyelinating disorder given this appearance. If the patient has a chronic illness such as hypertension or diabetes, that may account for this finding." Id. Petitioner has both hypertension and diabetes. Additionally, the radiologist did not specifically mention MS in his impression, and none of petitioner's treating physicians interpreted the MRI to support a diagnosis of MS.

Second, petitioner was tested for oligoclonal bands and was found to have none. See Pet. Ex. 12 at 25. Thus, Dr. Epperson found petitioner's MS profile negative.

Third, Dr. Epperson questioned whether petitioner could be suffering from a spinal cord compression and/or spinal cord infarction prior to the lumbar puncture or EMG/NCV studies. After these diagnostic tests were conducted, however, spinal cord compression and/or spinal cord infarction was no longer a differential.

Fourth, petitioner was found to have "electrophysiological evidence of a dysfunction of the bilateral [visual evoked potentials] systems" on February 13, 2013. Pet. Ex. 4 at 98. However, this finding alone is insufficient for a diagnosis of MS under the McDonald criteria. The McDonald criteria requires both dissemination in time and space. For both requirements, lesions on MRI are needed. Petitioner's brain and thoracic MRIs were not interpreted as showing MS lesions.

Lastly, none of petitioner's treating physicians diagnosed him with MS. For all of these reasons, petitioner does not meet the criteria for MS.

With regard to CIDP, as the undersigned explained above, it was only ever a differential diagnosis and/or compared to GBS in diagnosis. The records do not support an ultimate diagnosis of CIDP. Dr. Oh ruled out a CIDP diagnosis because he found no evidence of a significant relapse. Dr. Donofrio also did not support a CIDP diagnosis because he found the findings on petitioner's MRI and visual evoked potentials would not be expected in a CIDP patient. Also, Dr. Donofrio opined that petitioner's normal upper extremity reflexes are "highly unusual" for a CIDP patient.

CIDP is a slowly progressive demyelinating polyneuropathy, while GBS is an acute monophasic peripheral neuropathy. In October 2012, petitioner presented to the ER, Dr. Russell, and Dr. Epperson complaining of sudden leg weakness. Although continued IVIG treatments may be more consistently used to treat CIDP, the undersigned finds petitioner's diagnosis does not turn on this treatment.

Therefore, the undersigned finds there is not a more likely alternative diagnosis.

6. Supportive Evidence of GBS Diagnosis

The Vaccine Table Qualifications and Aids to Interpretation note that supportive, but not required, evidence of a GBS diagnosis "includes electrophysiologic findings consistent with GBS or an elevation of [CSF] protein with a total CSF white blood cell count below 50 cells per microliter." 42 C.F.R. at § 100.3(c)(15)(iv). Here, all of petitioner's diagnostic tests were supportive of a GBS diagnosis.

Petitioner underwent a lumbar puncture on October 15, 2012, which revealed elevated protein of 75 and a normal white blood cell count, consistent with GBS.

Petitioner underwent multiple EMG/NCV studies over the course of his illness. October 8, 2012 EMG/NCV testing found "severe diffuse neuropathy in the lower extremities and right upper extremity compatible with [GBS] versus a severe neuropathy from diabetes." Pet. Ex. 4 at 18. EMG/NCV studies from 2013 to 2020 were all compatible with GBS.

Dr. Oh found petitioner's CSF supportive of GBS and petitioner's EMG/NCV studies indicative of "a definite demyelinating neuropathy typical of GBS involving upper extremity and lower extremities." Pet. Ex. 32 at 1. Although all EMG/NCV tests were interpreted as consistent with GBS, Dr. Donofrio opined the results can also been seen in a severe diabetic polyneuropathy. He also opined elevated protein levels in CSF can be found in patients with diabetes and in MS patients. However, the totality of the evidence supports a diagnosis of GBS.

D. The Lookback Provision

Under the Vaccine Act, a person "who has sustained a vaccine-related injury" must file a claim within 36 months of the onset of the symptoms of the injury. § 16(a)(2). This period can be extended under § 16(b), which provides that "any time the Vaccine Injury Table is revised and the effect of such revision is to permit an individual who was not, before such revision, eligible to seek compensation under the Program, or to significantly increase the likelihood of obtaining compensation, such person may . . . file a petition for such compensation not later than [two] years after the effective date of the revision" provided the vaccine-related injury occurred within eight years before the date of the revision of the Table.

The Table was revised and became effective on March 21, 2017. This revision included GBS as an injury following administration of the seasonal flu vaccine. 42 C.F.R. § 100.3(a)(XIV)(D). For the lookback provision to apply, petitioner had until March 21, 2019, two

years after the effective date of the revision, to file his petition. Additionally, petitioner's vaccine-related injury must have occurred within eight years before the date of the revision, or by March 21, 2009.

Petitioner filed his petition on March 19, 2018. Petitioner received the flu vaccine at issue on September 12, 2012, and initial manifestation of onset occurred on or around October 1, 2012. The undersigned finds petitioner filed his petition within two years of the effective date of the revision for a vaccine-related injury that occurred within eight years before the date of the revision of the Table. Thus, under § 16(b), petitioner's petition was timely filed.

V. CONCLUSION

Based on the record as a whole and for the reasons discussed above, the undersigned finds there is preponderant evidence that petitioner's meets the Table criteria for GBS. Therefore, petitioner **GRANTS** petitioner's motion for a ruling on the record and finds petitioner entitled to compensation. A separate damages order will issue.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master